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ABSTRACT

This hearing addressed the issue of whether the delays in producing a proposed National Institute for Occupational and Safety Health (NIOSH) study on the possible health hazards associated with video display terminals (VDTs) are due to concerns about scientific methodology or unwarranted interference by the Office of Management and Budget (OMB). The following witnesses made statements before the committee: (1) Barbara J. Easterling, executive vice president, accompanied by David LeGrande, occupational safety and health representative, and Lou Gerber, legislative representative, Communications Workers of America; (2) James M. Melius, Director, Division of Surveillance, Hazard Evaluations and Field Studies, NIOSH, accompanied by Theresa Schnorr, NIOSH, and Gooloo Wunderlich, Public Health Service; (3) Hubert F. Owens, counsel, BellSouth Corporation, accompanied by Melissa Hess, industrial engineer, and Brian MacMahon, chairman of epidemiology at the Harvard School of Public Health. The following prepared statements, letters, and supplemental material were submitted in addition to the prepared statements of the above witnesses: (1) prepared statement on behalf of American Telephone and Telegraph, by James P. Dunn; (2) prepared statement on behalf of the Newspaper Guild, by Charles A. Perlik, Jr.; (3) letter by Karen Nussbaum, Service Employees International Union to Honorable Joseph M. Gaydos; and (4) letter by John J. Sweeney, Service Employees International Union, to Congressman Gaydos. (EW)

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NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH OVERSIGHT: OMB INVOLVEMENT IN VDT STUDY

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HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH AND SAFETY

OF THE

COMMITTEE ON EDUCATION AND LABOR
HOUSE OF REPRESENTATIVES

NINETY-NINTH CONGRESS

SECOND SESSION

HEARING HELD IN WASHINGTON, DC, JUNE 4, 1986

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CONTENTS

	Page
Hearing held in Washington, DC, June 4, 1986	1
Statements of:	
Easterling, Barbara J., executive vice president, accompanied by David LeGrande, occupational safety and health representative and Lou Gerber, legislative representative, Communications Workers of America	2
Melius, James M., Director, Division of Surveillance, Hazard Evaluations and Field Studies, NIOSH, accompanied by Theresa Schnorr, NIOSH; and Gooloo Wunderlich, Public Health Service	16
Owens, Hubert F., counsel, BellSouth Corp., accompanied by Melissa Hess, industrial engineer and Brian MacMahon, chairman of Harvard School of Public Health	35
Prepared statements, letters, supplemental materials, et cetera:	
Dunn, James P., prepared statement on behalf of AT&T	56
Easterling, Barbara J., executive vice president, prepared statement on behalf of Communications Workers of America	10
Melius, James, M., director, Division of Surveillance, Hazard Evaluations and Field Studies, NIOSH	19
Owens, Hubert F., counsel, BellSouth Corp	49
Perlik, Charles A., Jr., president, prepared statement on behalf of the Newspaper Guild (AFL-CIO, CLC)	55
Nussbaum, Karen, Service Employees International Union, AFL-CIO, CLC, letter to Hon. Joseph M. Gaydos	53
Sweeney, John J., Service Employees International Union, AFL-CIO, letter to Hon. Joseph M. Gaydos	53

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH OVERSIGHT: OMB INVOLVEMENT IN VDT STUDY

WEDNESDAY, JUNE 4, 1986

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND SAFETY,
COMMITTEE ON EDUCATION AND LABOR,
Washington, DC.

The subcommittee met, pursuant to call, at 9:30 a.m., in room 2261, Rayburn House Office Building, Hon. Joseph M. Gaydos (chairman of the subcommittee) presiding.

Members present: Representatives Gaydos, Murphy, and Hayes.

Staff present: Sy Holzman, deputy staff director; Lee Bassford, staff assistant; Dorothy L. Strunk, minority senior legislative associate.

Mr. GAYDOS. The committee will be in order.

Other members are on their way over, but I think because of time being of the essence we should proceed without them.

During the 1984 hearings by the Subcommittee on Health and Safety on the potential health hazards of video display terminals, no conclusive scientific evidence was presented to show that working with VDT's was or was not responsible for cases of spontaneous abortion, birth defects, or other health problems.

The committee report which summarizes those hearings, therefore, recommended additional studies to determine if there was any kind of direct relationship between the extensive use of VDT's and an assortment of health-related problems.

The concern was a simple one: to relieve a host of anxieties caused to those who believe VDT's create health problems or to pinpoint any problems and then take necessary steps to eliminate the health hazard or to reduce its intensity.

The study proposed by NIOSH, which was first brought to the subcommittee's attention during those 1984 hearings by Dr. J. Donald Millar, Director of NIOSH, has been strongly supported by the subcommittee staff in its report. In the time since the report was issued, which is August 1985, the NIOSH protocol has been reviewed internally and externally, has been submitted to and rejected by the Office of Management and Budget, has been revised and re-reviewed and just 2 weeks ago was again submitted to the OMB.

The subcommittee is intimately concerned about the inordinate delay in getting the study initiated. Certainly, if the concerns about the study were with the scientific methodology, then I am sure they can be addressed and corrected.

If, however, the delays are aimed at squelching the study, then, of course, that presents a different concern.

I have often said we must have employers before we can have employees. That is fundamental and basic. Still, employers have a responsibility to insure that employees have a safe and healthy work environment, within reasonable conditions.

If this study will enable us to determine whether VDT's cause some kinds of problems or they do not cause them, then we will all be better off for it.

The goal of today's hearing is to determine what has caused the delay in winning approval of this study and whether an inordinate amount of influence was wielded to delay it.

With those opening remarks, the Chair will call the first witness, and the first witness will be Barbara J. Easterling, executive vice president; David LeGrande, occupational safety and health representative; and Lou Gerber, legislative representative, all from the Communications Workers of America.

So, welcome to the committee and among yourselves determine who starts off and proceeds in a manner that best serves your purposes, and without objection at this time—of course, there is none—your written testimony as presented to the committee will be made formally part of the committee record.

Welcome to the committee and you may proceed.

STATEMENT OF BARBARA J. EASTERLING, EXECUTIVE VICE PRESIDENT, COMMUNICATIONS WORKERS OF AMERICA, ACCOMPANIED BY DAVID LeGRANDE, OCCUPATIONAL SAFETY AND HEALTH REPRESENTATIVE; AND LOU GERBER, LEGISLATIVE REPRESENTATIVE

Ms. EASTERLING. Good morning, Mr. Chairman and other members of the subcommittee.

I am Barbara J. Easterling, executive vice president of the Communications Workers of America. Accompanying me today are David LeGrande, a CWA occupational safety and health representative, and Lou Gerber, our CWA legislative representative.

Our organization represents more than 650,000 private and public sector workers who live in all 50 States and in more than 10,000 communities throughout the Nation.

Of special interest, CWA represents over 400,000 workers who use video display terminals, VDT's, to perform their jobs. In fact, CWA represents more VDT operators than any labor organization in the United States. Moreover, we anticipate that the number of wage earners whom we represent who work with VDT's will grow in the future.

CWA commends you and the subcommittee for focusing the congressional spotlight on the significant question of whether exposure to VDT's poses a threat to the health and safety of the American work force. We are well aware of the pioneering role this committee has played in investigating the relationship between VDT's and the well-being of wage earners. That issue is emerging as one of the most important workplace concerns of the 1980's. Presently, 17 million Americans, 11 percent of the civilian employee population, work at video display terminals. It has been forecast that by 1990

40 million workers in the United States will make their living by using VDT's.

Turning to today's topic. CWA is concerned that a study proposed by the National Institute for Occupational Safety and Health [NIOSH], which would examine links between work with VDT's and possible increased risks of adverse pregnancy outcomes among female telephone workers, may be squelched due to opposition expressed by the BellSouth Corp. and the Office of Management and Budget. CWA represents the population NIOSH wishes to examine as to potential reproductive hazards associated with VDT's.

Ironically, it was 2 years ago that Dr. J. Donald Millar, Director of NIOSH, appeared before this subcommittee and advised that such a study had high priority because of additional reports of problem pregnancies.

Mr. Chairman, the disturbing question of whether a cause-effect or contributory relationship exists between VDT use and abnormal pregnancies continues to cast a cloud of doubt over our Nation's offices and workplaces. A Government-sponsored study could shed light on whether VDT's pose no danger to their operators or whether these efficient machines are incubators for tragedy. Refusal to conduct such an objective scientific inquiry could have a chilling effect on the right of female VDT operators to know if they are unwittingly jeopardizing their ability to bear normal children by carrying out their job duties.

Adverse pregnancy outcomes possibly linked to VDT use could include spontaneous abortions, stillbirths, premature births, birth defects, neonatal death and infant respiratory disease.

During the last 6 years, scientists have identified 12 clusters of negative pregnancy outcomes among VDT operators in the United States and Canada. Of special concern to CWA, two of these clusters included workers represented by our union.

Because of growing interest in this issue and lack of scientific data, NIOSH announced plans in late 1982 to conduct a study of reproductive risks among VDT operators. During 1983 and much of 1984, NIOSH gave consideration to potential populations for such a study and developed a questionnaire to be used in carrying out its investigation. After deciding that the telecommunications industry presented the most appropriate population for such an inquiry, NIOSH began to meet with representatives from CWA and with officials from what was still then the Bell System.

In December 1984, NIOSH convened a public hearing in which CWA participated, including Mr. LeGrande, along with business representatives and scientific researchers to review a detailed draft of a study proposal.

During 1985 NIOSH held several meetings involving representatives from CWA, AT&T and BellSouth for the purpose of finalizing the NIOSH protocol. In late 1985 NIOSH submitted its completed protocol to the Office of Management and Budget for its review, in accordance with Federal law.

Mr. Chairman, CWA's 5-year effort to obtain an objective, scientific, Government-sponsored study of possible links between VDT use and reproductive hazards came to a screeching halt on December 12, 1985, when OMB disapproved the NIOSH protocol, alleging flaws in the study's design.

OMB's criticisms of the NIOSH protocol appear to reflect objections set forth by the BellSouth Corp. whose employees would comprise part of the study population. More specifically, the OMB rejection paralleled exceptions articulated by two professors who were retained by BellSouth to prepare a critique of the NIOSH proposal.

That critique, paid for by BellSouth, raises a public policy question. Does the telephone company make proper use of its residential customers' dollars—particularly those of female rate payers—when it spends their money to cross-subsidize a study used to obstruct a Government proposal which could benefit female telephone customers who also are VDT operators?

Indeed, CWA apparently has a different perception of the purpose of the NIOSH protocol than does that regional Bell operating company.

In a letter dated November 5, 1985, Mr. Roy B. Howard, assistant vice president for industrial relations at BellSouth, wrote to Mrs. Wendy L. Gramm, Administrator for Information and Regulatory Affairs at OMB, as follows, and I quote:

> We are concerned, however, that the proposed study, as currently designed, will not provide reliable and useful scientific information and will not achieve NIOSH's principal goal which is to allay public and employee concern over the possible effects of VDT's.

By contrast with this viewpoint, CWA contends that the purpose of the NIOSH protocol is to effectuate an objective inquiry that analyzes the empirical data and follows the evidence to whatever conclusion arises from rigorous scientific research. We do not believe it is the role of the telephone company to proclaim a conclusion and then urge that NIOSH carry out a study that legitimizes a rosy premise. The well-being of women workers is too important to be sacrificed on the altar of anything less than a comprehensive investigation.

Mr. Chairman, we do take heart from the fact that NIOSH has prepared a revised protocol for OMB's review. Approval of this second protocol has taken an agonizingly long time. This has been due, in part, we believe, to continued attempts by BellSouth to obstruct or shape the study. While NIOSH waits, hundreds of thousands of CWA members and millions of other female VDT operators continue to suffer potentially hazardous effects on their reproductive capacities.

In addition to CWA, Government, labor and management organizations have expressed broad-gauged support for an inquiry into VDT reproductive hazards. Recently, the Office of Technology Assessment of Congress issued a report on the "Automation of America's Offices." In that report, OTA concluded that continued research is necessary to examine if a link exists between VDT use and reproductive outcome, due to a dearth of data.

Similarly, other labor unions, representing millions of VDT operators, support the carrying out of a Government investigation that will seek to determine if there is a relationship between VDT use and reproductive disorders.

Of special interest, the Computer and Business Equipment Manufacturers Association, CBEMA, has also indicated support for such a study, and that association includes such major American corpo-

rations as AT&T, IBM, Digital Equipment, National Cash Register, Hewlett-Packard, and Xerox. In addition, the American Newspaper Publishers Association, the Air Transport Association and the American Council of Life Insurance believe a study is necessary to develop a more complete scientific data base.

Most recently, laboratory studies reviewed at the International Conference on Work With Display Units in Stockholm, Sweden, last month indicated some evidence of reproductive effects in several cases relevant to VDT's. Of significant importance, a Swedish study found malformations among mice exposed to VDT-type radiation and Finnish scientific investigators reported malformations among chick embryos exposed to VDT-like electromagnetic fields. Similarly, epidemiological studies showed some evidence of higher rates of birth defects or spontaneous abortions among VDT operators.

Although there is controversy regarding the interpretation of these studies, they point out the need to resolve the question of whether there is a relationship between negative reproductive outcomes and VDT use. As a result of such controversy and increased fear among millions of VDT operators, the initiation and completion of the NIOSH VDT reproductive hazards study becomes even more important.

As previously noted, the NIOSH study would provide important answers to the potential causes of VDT workers' negative reproductive outcomes.

In summary, NIOSH's research could help determine whether any relationship exists between VDT use and reproductive outcome. CWA contends that the Federal Government should act to ensure that VDT operators are provided safe and healthful working conditions.

Mr. Chairman, to help accomplish this important goal, our union urges the Subcommittee on Health and Safety to endorse the NIOSH VDT reproductive hazard study; encourage support for the inquiry by all governmental agencies that are empowered to review it; ensure that adequate funds are authorized to conduct the VDT investigation; monitor closely the NIOSH research study so that the agency is able to conduct the best possible scientific inquiry into the impact, if any, that VDT's may have on female users of these machines; and pursue a thorough examination of whether VDT's endanger the safety and health of the American work force.

In conclusion, CWA commends the subcommittee for holding this hearing. We appreciate your interest in this vital matter and your willingness to place the issue of potential reproductive hazards associated with the use of video display terminals under the legislative branch's microscope.

Thank you.

Mr. GAYDOS. Those accompanying you, are they going to give a statement?

Ms. EASTERLING. They are not going to give a statement, but we are available for questions.

Mr. GAYDOS. Let me ask this question. Do you have any problems with costs involved in this study? Do you think cost is an important factor? We know it is important under certain budgetary restraints

in the Government, but what about the cost? What are we talking about here?

Mr. GERBER. Mr. Chairman, it is our understanding the cost of the study has been estimated at about $363,000 for the 2-year study. We do not believe that within the scope of the budget the cost is excessive or a major factor.

Mr. GAYDOS. Would you be aware that some short 6 months ago or 1 year ago they were talking about an overall cost of roughly $150,000? So it has accelerated since then.

Ms. EASTERLING. Yes.

Mr. GAYDOS. Do you agree with me when I would make the conclusion or the observation that the costs relative to the problem are very reasonable?

Ms. EASTERLING. Absolutely.

Mr. GAYDOS. When we talked about 17 million workers that are exposed—is that my correct understanding—to display terminals in one form or another, what percentage of those are women? Would your statistics show? Are we talking about primarily mostly women or is that shared equally between male and female?

Ms. EASTERLING. Very high percentage female.

Mr. GAYDOS. We could very easily apply the statistics of births in that area. We would be talking about roughly so many births involved, potential births in that working category; is that right?

Ms. EASTERLING. That would be correct.

Mr. GAYDOS. Personally, you are familiar with the hearings and the complete study that the committee had reported in the bound volume. Have you had an opportunity to go over that?

Ms. EASTERLING. Yes, I have.

Mr. GAYDOS. Any of your subordinates have?

Ms. EASTERLING. Yes.

Mr. GAYDOS. Do you share my conclusion that it is indecisive insofar as whether we have a problem or not? Based upon those hearings, the data in there, is that an accurate observation by the committee?

Ms. EASTERLING. Yes.

Mr. GAYDOS. But we do have sufficient, in my opinion—and I do not know if my committee members share it—but in my opinion we do have sufficient data based on comparisons of foreign studies such as the Sweden report that it would justify a study to be made. Would you share that opinion with me?

Ms. EASTERLING. Correct.

Mr. GAYDOS. Let me ask you a personal question if you have an opinion. You suit yourself whether you want to respond or not. Why in your opinion, if you have one, would anyone, any business, any individual, any group, any association, if any, delay or attempt to block this study? Could you give the committee your feelings on that or your observations, if that is the case or if it would be the case. What would be the justification to do that based on your experience in the past dealing with like problems in situations where you have run up against a so-called stone wall and recalcitrance on the part of the individuals involved? Do you think that is the case here, that we have a problem and somebody is trying to block this study for their own aggrandizement or personal purposes or do you

think it is just a matter of different opinions and different positions?

Ms. EASTERLING. Well, in one of the letters that BellSouth sent to Dr. Donald Millar, they indicated that they have a large investment in the terminals, so they have a large investment in equipment that is now in place; so that should the study be an adverse study, it would require them to replace that equipment. In addition, I imagine that they would be a little bit leary of what might occur in the legal arena should that be found, that women do, in fact, have harmful pregnancies. They would be looking at the legal aspects as well.

Mr. GAYDOS. If I may paraphrase then, No. 1, cost of replacement of the equipment and, No. 2, possibly the fact they may have some legal ramifications, suits and workmen's comp; is that right?

Ms. EASTERLING. Yes.

Mr. GAYDOS. It is understood that for a variety of reasons the prospective part of the study cannot be done, as we understand it, as distinguished from the retrospective aspect of it. Do you have an opinion as to whether this would diminish the value of the study if it is done?

Mr. LEGRANDE. Mr. Chairman, it would be most appropriate if there were both retrospective and prospective phases of the study. Unfortunately, given the change from the light-emitting diode equipment to the VDT technology by AT&T, the control group will be eliminated. We find it somewhat ironic that the further the delay regarding the initiation and completion of this study the more difficult it becomes to even do some of the retrospective phases of the study, and thus our contention the study should move along as quickly as possible.

Mr. GAYDOS. The last question I have and I will call on Mr. Murphy.

Looking at the revised protocol submitted and approved at the various levels within the Department of Health and Human Services, are you of the opinion that the proposed study would meet scientifically acceptable criteria and that the data would be valid and useful?

Ms. EASTERLING. Yes.

Mr. GAYDOS. Do you see any flaws in the study in the design?

Ms. EASTERLING. No, we do not.

Mr. GAYDOS. I want to thank you very much.

At this time the Chair would like to call on Mr. Murphy who chairs a corresponding committee.

Mr. Murphy.

Mr. MURPHY. Thank you, Mr. Chairman.

I would just like to ask one question. The NIOSH study, as I understand it, would have merely been sending out questionnaires to about 3,000 operators, some of whom were working the video terminals and some who were not. Could your union do that? Could you conduct such a survey? Have you thought about that?

Ms. EASTERLING. We had thought about that, but who would accept it then? Would the company? Certainly it would be a questionable study on the part of the company, and it would be publicly questionable by other companies. That is the reason we are so

intent on NIOSH, being an unbiased third party, handling it completely, just as we are very questionable about BellSouth——

Mr. MURPHY. Even if we may agree, BellSouth comes in and they bring in their experts and if you brought in your survey, at least you are no further behind and you may be even at that point if you have a survey that shows anything. What I am suggesting to you is unless we can overcome the dilemma with NIOSH and OMB, we have nothing. So consider it.

Ms. EASTERLING. Certainly.

Mr. MURPHY. Thank you.

Thank you, Mr. Chairman.

Mr. GAYDOS. Before you leave, I am sure your data and your records are complete and up to date. Could you as a practical matter inform the committee if you had any recent complaints from any worker that they may think or might be suspicious in their own mind, layman's observations, that they have had some problems with VDT's? Can you relate any of those, if you have any?

Mr. LEGRANDE. Mr. Chairman, as reported in the testimony, we do represent two clusters of the reproductive, negative reproductive outcomes: one in Renton, WA, locale of Seattle, employees employed by Pacific Northwest Bell; another in Atlanta, GA, employees working for BellSouth or Southern Bell, in this case. In addition, we have several unsubstantiated, that is, unsubstantiated from a scientific viewpoint, clusters throughout the United States.

Clearly among our more than 400,000 VDT operators, of which some 90 to 95 percent are women, this is the key question in their minds. Is there reproductive harm?

Mr. GAYDOS. I just want to apprise you of the fact that before you respond that what bothers me in having sat through these hearings is we had the display terminals right on that table that you are sitting at and we had experts come in; and specifically and repeatedly I would ask questions, are there any rays coming out of those VDT's and what are the problems? And every expert, every one of them before the committee, said there are no rays, no nothing, and they are perfectly safe, et cetera, went into a long, elongated explanation. I just want you to know that. We did have the problem of furniture, you know, as to eyestrain and things of that nature; but on that question which I repeatedly pressed, that was the response.

I am sure you read the record very thoroughly, and you find maybe the record is deficient in that area, but I tried to with all of the paraphernalia I had available to me to make sure that record was clear, and with the possibility of boring the witnesses I kept asking the question from all different angles so we would not have any question at all as to what the record said in response to that specific question: Will this affect pregnant women? Go ahead.

Mr. LEGRANDE. Mr. Chairman, we commend you for the hearings that you conducted in 1983 and 1984 and then again those today and commend you for the report that came out of that and the advancements that had been made as a result of that activity. As we stated in 1984, there are not any answers—adequate, scientific, conclusive answers—to address the issue of negative reproductive outcomes or the lack thereof. As stated back in 1984, at that point there was not available scientific equipment that was being used in

the field to measure the type of radiation that is believed to be associated with reproductive harm; that is, very low frequency radiation. That equipment is now available.

In fact, a year ago last November, our union filed a health hazard evaluation with the National Institute for Occupational Safety and Health, and it was in November NIOSH saw fit to contract with Dr. William Guy at the University of Washington, who, incidentally, conducted a study using VLF-type equipment for IBM and found older equipment that was not shielded per the FCC guidelines should be shielded because it could emit higher than supposed safe—although no one knows what safe is—levels of radiation.

What that suggests is the technology is now available to be implemented in the field to determine whether there is, indeed, a problem with the radiation emissions. Back in 1984 the data that was being thrown out as being conclusive was not at all conclusive because it did not contain measurements in the VLF field.

Mr. GAYDOS. Let me thank you. I think that is one of the key points. I think you have succinctly put on record—and that is why I asked you the question—the reason why we are here and the difference between the situation then and as it exists now; and in conclusion I want to thank all of you very profusely and repeatedly for your past cooperation. You have always made available data you had. You never tried to infer that it stood for anything more than it was. You have been very cooperative. I want you to know the committee is most appreciative.

Any other items you want to spread on the record?

Ms. EASTERLING. I have some of the additional data that I will be glad to provide to the committee.

Mr. GAYDOS. Could you sum it? What does it say?

Ms. EASTERLING. We have already introduced it, dealing with the clusters.

Mr. GAYDOS. Without objection, that prepared data will also be made part of the permanent record in this matter and appear in the record.

[Prepared statement of Barbara J. Easterling with attachments follows:]

PREPARED STATEMENT OF BARBARA J. EASTERLING, EXECUTIVE VICE PRESIDENT, COMMUNICATIONS WORKERS OF AMERICA

Good morning, Mr. Chairman and other members of the Subcommittee.

I am Barbara J. Easterling, Executive Vice President of the Communications Workers of America. I have the privilege of serving as the highest-ranking female official of our national Union. My duties at CWA include administering the Union's Government Relations activities in Washington, D.C. Accompanying me today are David LeGrande, CWA Occupational Safety and Health Representative, and Lou Gerber, CWA Legislative Representative.

Our organization represents more than 650,000 private and public sector workers who live in all 50 states, in each of the 435 Congressional Districts and in more than 10,000 communities throughout the nation.

Of special interest, CWA represents over 400,000 workers who use video display terminals (VDTs) to perform their jobs. In fact, CWA represents more VDT operators than any labor organization in the United States. Moreover, we anticipate that the number of wage earners whom we represent who work with VDTs will grow in the future.

CWA commends you and the Subcommittee for focusing the Congressional spotlight on the significant question of whether exposure to VDTs poses a threat to the health and safety of the American workforce. We are well aware of the pioneering role this panel has played in investigating the relationship between VDTs and the well-being of wage earners. That issue is emerging as one of the most important workplace concerns of the 1980s. Presently, 13 million Americans, 11 percent of the civilian employee population, work at video display terminals. It has been forecast that by 1990 40 million workers in the United States will make their living by using VDTs.

Turning to today's topic, CWA is concerned that a study proposed by the National Institute for Occupational Safety and Health (NIOSH), which would examine links between work with VDTs and possible increased risks of adverse pregnancy outcomes among female telephone workers, may be squelched due to opposition expressed by the Bell South Corporation and the Office of Management and Budget. CWA represents the population NIOSH wishes to examine as to potential reproductive hazards associated with VDTs.

Ironically, it was two years ago that Dr. J. Donald Millar, Director of NIOSH, appeared before this Subcommittee and advised that such a study has high priority because of additional reports of problem pregnancies.

Mr. Chairman, the disturbing question of whether a cause-effect or contributory relationship exists between VDT use and abnormal pregnancies continues to cast a cloud of doubt over our nation's offices and workplaces. A government-sponsored study could shed light on whether VDTs pose no danger to their operators or whether these efficient machines are incubators for tragedy. Refusal to conduct such an objective scientific inquiry could have a chilling effect on the right of female VDT operators to know if they are unwittingly jeopardizing their ability to bear normal children by carrying out their job duties.

Adverse pregnancy outcomes possibly linked to VDT use could include spontaneous abortions, stillbirths, premature births, birth defects, neonatal death and infant respiratory disease.

During the last six years, scientists have identified 12 clusters of negative pregnancy outcomes among VDT operators in the United States and Canada. Of special concern to CWA, two of these clusters included workers represented by our Union.

Because of growing interest in this issue and lack of scientific data, NIOSH announced plans in late 1982 to conduct a study of reproductive risks among VDT operators. During 1983 and much of 1984, NIOSH gave consideration to potential populations for such a study and developed a questionnaire to be used in carrying out its investigation. After deciding that the telecommunications industry presented the most appropriate population for such an inquiry, NIOSH began to meet with representatives from CWA and with officials from what was still then the Bell System.

In December, 1984, NIOSH convened a public hearing in which CWA participated, including, Mr. LeGrande, along with business representatives and scientific researchers to review a detailed draft of a study proposal.

During 1985, NIOSH held several meetings involving representatives from CWA, AT&T and Bell South for the purpose of finalizing the NIOSH protocol. In late 1985, NIOSH submitted its completed protocol to the Office of Management and Budget for its review, in accordance with federal law.

Mr. Chairman, CWA's five-year effort to obtain an objective, scientific, government-conducted study of possible links between VDT use and reproductive hazards came to a screeching halt on December 12, 1985, when OMB disapproved the NIOSH protocol, alleging flaws in the study's design.

OMB's criticisms of the NIOSH protocol appear to reflect objections set forth by the Bell South Corporation whose employees would comprise part of the study population. More specifically, the OMB rejection paralleled exceptions articulated by two professors who were retained by Bell South to prepare a critique of the NIOSH proposal.

That critique, paid for by Bell South, raises a public policy question. Does the telephone company make proper use of its residential customers' dollars -- particularly those of female ratepayers -- when it spends their money to cross-subsidize a study used to obstruct a government proposal which could benefit female telephone customers who also are VDT operators?

Indeed, CWA apparently has a different perception of the purpose of the NIOSH protocol than does that regional Bell operating company.

In a letter dated November 5, 1985, Mr. Roy B. Howard, Assistant Vice President for Industrial Relations at Bell South, wrote to Mrs. Wendy L. Gramm, Administrator for Information and Regulatory Affairs at OMB, as follows:

> "We are concerned, however, that the proposed study, as currently designed, will not provide reliable and useful scientific information and will not achieve NIOSH's principal goal which is to allay public and employee concern over the possible effects of VDTs." (emphasis added)

By contrast with this viewpoint, CWA contends that the purpose of the NIOSH protocol is to effectuate an objective

inquiry that analyses the empirical data and follows the evidence to whatever conclusion arises from rigorous scientific research. We do not believe it is the role of the telephone company to proclaim a conclusion and then urge that NIOSH carry out a study that legitimizes a rosy premise. The well-being of women workers is too important to be sacrificed on the altar of anything less than a comprehensive investigation.

Mr. Chairman, we do take heart from the fact that NIOSH has prepared a revised protocol for OMB's review. Approval of this second protocol has taken an agonizingly long time. This has been due, in part, we believe, to continued attempts by Bell South to obstruct or "shape" the study. While NIOSH waits, hundreds of thousands of CWA members and millions of other female VDT operators continue to suffer potentially hazardous effects on their reproductive capacities.

In addition to CWA, government, labor and management organizations have expressed broad-gauged support for an inquiry into VDT reproductive hazards. Recently, the Office of Technology Assessment of Congress issued a report on the Automation of America's Offices. In that report, OTA concluded that continued research is necessary to examine if a link exists between VDT use and reproductive outcome, due to a dearth of data.

Similarly, other labor unions, representing millions of VDT operators, support the carrying out of a government investigation that will seek to determine if there is a relationship between VDT use and reproductive disorders.

Of special interest, the Computer and Business Equipment Manufacturer's Association (CBEMA), has also indicated support for such a study. That association includes such major American corporations as AT&T, IBM, Digital Equipment, National Cash Register, Hewlett-Packard and Xerox. In addition, the American Newspaper Publishers Association, the Air Transport Association and the American Council of Life Insurance believe a study is necessary to develop a more complete scientific data base.

In summary, NIOSH's research could help determine whether any relationship exists between VDT use and reproductive outcome. CWA contends that the Federal Government should act to insure that VDT operators are provided safe and healthful working conditions.

Mr. Chairman, to help accomplish this important goal, our Union urges the Subcommittee on Health and Safety to:

- Endorse the NIOSH VDT reproductive hazards study;
- encourage support for the inquiry by all governmental agencies that are empowered to review it;
- insure that adequate funds are authorized to conduct the VDT investigation;
- monitor closely the NIOSH research study so that the agency is able to conduct the best possible scientific inquiry into the impact, if any, that VDTs may have on female users of these machines;
- and pursue a thorough examination of whether VDTs endanger the safety and health of the American workforce.

In conclusion, CWA commends the Subcommittee for holding this hearing. We appreciate your interest in this vital matter and your willingness to place the issue of potential reproductive hazards associated with the use of video display terminals under the Legislative Branch's microscope.

Thank you.

Laboratory studies reviewed at the "International Conference On Work With Display Units" in Stockholm, Sweden, May 12-15 indicated some evidence of reproductive effects in several cases relevant to VDTs. Of significant importance, a Swedish study found malformations among mice exposed to VDT-type radiation and Finnish scientific investigators reported malformations among chick embryos exposed to VDT-like electromagnetic fields. Similarly, several epidemiological studies showed some evidence of higher rates of birth defects or spontaneous abortions among VDT operators.

Although there is controversy regarding the interpretation of these studies, they point out the need to resolve the question of whether there is a relationship between negative reproductive outcomes and VDT use. As a result of such controversy and increased fear among millions of U. S. VDT operators, the initiation and completion of the NIOSH VDT reproductive hazards study becomes even more important. As previously noted, the NIOSH study would provide important answers to the potential causes of VDT workers' negative reproductive outcomes.

CWA VDT REPRODUCTIVE CLUSTERS

One involves members of CWA Local 9103 in Renton, Washington. During an 18 month period between 1980 and 1981, three out of three pregnancies of women employed by Pacific Northwest Bell in one of the company's work locations had adverse outcomes. One member gave birth to a mongoloid child, another's child was born with an open spine, and the remaining woman's child was stillborn. Although an investigation was conducted, no definitive causal factors were identified.

An additional cluster was comprised of six members of CWA Local 3204 in Atlanta, Georgia. Specifically, during 1983, six miscarriages out of a total 15 pregnancies occurrred among women employed by Southern Bell in one of its work locations. NIOSH conducted an investigation, but it found no causal agent.

Reported Cases of Reproductive System Outcomes in Computer-Mediated Workplaces by Work Site and Job

Company (city, date)	Job	Outcomes	
		VDT	Non-VDT
Sears-Roebuck/ Dallas, TX (5/79-5/80)	Financial records processing clerk[a]	3 miscarriages 4 full-term[b]	5 miscarriages 1 premature birth 9 full-term
Toronto Star/ Toronto, Ontario (5/79-5/80)	Classified ads processing clerks	4 birth defects	3 full-term
Air Canada/ Montreal, Quebec (2/79-4/81)	Part-time ticket agents	7 miscarriages 8 full-term	NIA[c]
Defense Department/ Marietta, GA (10/79-10/80)	NIA	3 birth defects 7 miscarriages 5 full-term	NIA
Defense Department/ Marietta, GA (10/80-10/81)	NIA	14 full-term	NIA
Pacific Northwest Bell Telephone/ Reston, WA (7/80-12/81)	NIA	2 birth defects 1 still born	NIA
Solicitor General Offices/Ottowa, Ontario (4/79-4/82)	NIA	4 miscarriages 1 premature 2 respiratory diseases	1 full-term
Surrey Memorial Hospital-Vancouver, British Columbia (1978-82)	Accounting department clerks	3 miscarriages 1 birth defect 1 premature 1 bronchitis/full-term 1 full-term	NIA
Toronto, Old City Hall, Ministry of Attorney General (1980-81)	Clerks Secretaries	10 miscarriages 9 full-term	NIA
United Airlines/ San Francisco, CA (1964)	Airline reservation clerk	23 miscarriages 61 full-term[d]	NIA
Southern Bell Telephone/Atlanta, GA (3/81-9/83)	Telephone operators	7 miscarriages 15 full-term	26 miscarriages 159 full-term
General Telephone/ Alma, MI (1983-84)	Telephone operators	12 miscarriages 2 still births 3 premature 15 full-term	NIA
Library/ Aarhus, Denmark	NIA	8 miscarriages 2 full-term	NIA
Department of Public Employees/Runcorn, England (1974-82)	Full-time VDT operators	8 miscarriages 4 still births 12 malformations	NIA

[a]Compares only full-time VDT operators with non-VDT operators who may have worked as much as 6 hours per month at the terminal.
[b]Full-term refers to the healthy delivery of a newborn after three trimesters. These are commonly termed live births.
[c]NIA means no information reported.
[d]This excludes 23 induced abortions and 9 full-term deliveries of wives of employed men.

Ms. EASTERLING. Finally, in discussions that we have had we viewed what you are attempting to do as probably like the steps that were taken years ago when people stood around and talked about the hazards of smoking, and it took a lot of testing and a lot of time by a lot of people to arrive where we are today and see the serious hazards of smoking and the cause-effect relationship and one we see very applicable to this issue. So, we again thank you very much for your support.

Mr. GAYDOS. Let the record show that the committee has had numerous inquiries asking for our testimony as being the only source of information dealing with VDT's. I mean with the problem. We have been repeatedly informed there is no place and no source, no library anyplace involving the problem as we had conceived it and as we developed in the hearings. So, as to the value of the report, I would say that the committee's time was well spent; and as to the conclusion of the report and the material contained therein, it is questionable.

At least one thing, it serves as a basis as to these continued hearings, and I want you to know the committee feels committed to the proposition we shall continue these hearings until we resolve this one way or another through an official study to the satisfaction of all those that are concerned and to the committee's satisfaction.

Thank you for participating.

Mr. GAYDOS. Next is the panel from the National Institute for Occupational Safety and Health, Department of Health and Human Services. The witnesses will be Dr. James Melius, Director, Division of Surveillance; Dr. Theresa Schnorr, NIOSH; and Dr. Gooloo Wunderlich, Public Health Service.

Welcome to the committee, gentleman and gentleladies, and you may proceed in the manner that best serves your purposes; and without objection, at this time your prepared testimony as submitted to the committee will be made part of the permanent record. So ordered.

Who will be the spokesman?

Dr. MELIUS. I will be speaking.

STATEMENT OF JAMES M. MELIUS, M.D., DIRECTOR, DIVISION OF SURVEILLANCE, HAZARD EVALUATIONS AND FIELD STUDIES, NIOSH, ACCOMPANIED BY THERESA SCHNORR, NIOSH; AND GOOLOO WUNDERLICH, PUBLIC HEALTH SERVICE

Dr. MELIUS. Mr. Chairman, members of the subcommittee.

I am Dr. James Melius, Director of the Division of Surveillance, Hazard Evaluations and Field Studies for NIOSH. We thank you for inviting us here today to discuss our reproductive health study of workers using video display terminals. With me today are Dr. Theresa Schnorr, an epidemiologist on my staff and the senior project officer for this research effort, and Dr. Gooloo Wunderlich of the Office of Health Planning and Evaluation for the Public Health Service.

Since our testimony has been submitted for the record, I would like to briefly summarize what we are saying.

Mr. GAYDOS. Sure.

Dr. MELIUS. In May 1984, NIOSH testified before your subcommittee regarding our research on the health issue of VDT use. At that time we indicated that we were planning to conduct a study investigating the effects of VDT use on reproductive health. We appreciate this opportunity to bring you up to date on our progress with this study.

We decided to conduct the study because of concern that VDT use may be hazardous to the reproductive health of women. Although several research efforts have looked at the possibility of an association between VDT use and adverse reproductive outcomes, none have resolved the issue; most have studied too few workers to enable scientists working in this area to have sufficient confidence in their findings. Given the limitations of these studies, we decided it was important for NIOSH to conduct a sound epidemiologic study of a large number of working women who use video display terminals, including an appropriate comparison group. We expect this study will enable us to determine whether there is a relationship between VDT use and adverse reproductive outcomes.

NIOSH is in a unique position to conduct this type of study for two reasons: one, we have developed considerable expertise on the health effects of VDT's. We have conducted surveys and clinical and laboratory studies to determine the ergonomic and visual effects of VDT use, and we have also conducted studies to determine the effects of use on stress experienced by workers.

Second, we have the authority, given in the Occupational Safety and Health Act, to investigate occupational health problems. We are the only public health research organization legally empowered to enter the work place and investigate working conditions and to access and review company records associated with these conditions.

We began looking for a possible study population for this research in 1982. We consulted many potential user groups, including international unions, State and Federal agencies, and industry groups. These included several potential study populations, such as the insurance industry, airline reservation offices, the telecommunications industry, and the Social Security Administration. After more than 2 years of searching and evaluating potential study populations, we determined that BellSouth and AT&T telecommunications companies at their facilities in the Southeast would give us the best scientific basis for success with this study.

We selected these study groups for several reasons. First, BellSouth employs a large number of female employees who spend most of their day working at VDT's. AT&T provides a large number of female employees who do similar work but without using VDT's. The size of these two groups, approximately 2,000 each, provides a sufficient number of women of child-bearing age to be able to detect a 50 percent or greater increased risk of miscarriages in the exposed group, if such a risk exists. Also, personnel records are available for both worker groups, and the method for studying the groups is logistically uncomplicated because the workers are located in a limited geographic area.

As is required for all major NIOSH research, the protocol for this study has received extensive peer review, which was conducted in public with the opportunity for public comment. The peer review

group for this study consisted of six scientists, four of whom were from outside NIOSH. They included three epidemiologists with expertise in reproductive studies, one statistician, and two experts in the areas of stress and ergonomics. In December 1984, we held an open meeting, announced in advance in the Federal Register, to peer review this study protocol. The meeting included representatives from BellSouth and AT&T and labor groups.

Based on the recommendations obtained as a result of the public peer review session, we revised the protocol and submitted it to the Human Subjects Review Board. After receiving their approval in May 1985, we submitted the protocol to the Office of Management and Budget for its approval as required by the Paperwork Reduction Act of 1980. Under implementing regulations for this law, OMB must approve any federally conducted or sponsored efforts to collect information on identical items from ten or more individuals or organizations. This covers a wide variety of activities, including surveys to gather data for biomedical and behavioral research.

Prior to the submission to the Department and OMB, all proposals for information collection by PHS agencies are reviewed by the PHS Reports Clearance Officer, who is responsible for the policy, administrative, and technical aspects of the OMB approval process in PHS. These proposals are reviewed for technical quality; compliance with PHS, Department, and OMB standards; policies and procedures; and for consistency with administration budget and management goals. We provided further details on this review process in our testimony.

PHS approved the OMB clearance package for the NIOSH VDT study on September 5, 1985, and forwarded it to the Office of the Assistant Secretary for Management and Budget for the Department, who subsequently forwarded it to OMB on September 27, 1985. In November, NIOSH and OMB were contacted in writing by BellSouth concerning questions they had regarding the study. In December 1985, OMB notified us that it had disapproved the study on the grounds of methodologic deficiencies, but indicated that CDC had made a credible case for conduct of a study.

In response to the concerns raised by OMB and BellSouth, we made several changes in the study protocol. These changes for the most part were clarifications and amplifications of aspects of our study questioned by OMB and BellSouth. The basic study design has not changed. We then sent the revised protocol to the original peer review panel and to the involved companies and labor unions for their further comment. The revised protocol responds to many of the concerns raised by BellSouth and has now been resubmitted through CDC, PHS, and the Department to the Office of Management and Budget.

We believe we have a scientifically sound study that will be valuable in evaluating this important public health issue. The peer review and HSRB review processes have provided us with extensive scientific review, and we believe the current study design appropriately addresses the concerns raised by BellSouth and OMB.

This concludes my testimony. We will be glad to answer any questions.

[Prepared statement of James M. Melius follows:]

PREPARED STATEMENT OF JAMES M. MELIUS, M.D., DIRECTOR, DIVISION OF SURVEILLANCE, HAZARD EVALUATIONS AND FIELD STUDIES, NIOSH

Mr. Chairman and Members of the Subcommittee:

I am Dr. James M. Melius, Director of the Division of Surveillance, Hazard Evaluations and Field Studies of the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control. Thank you for inviting us to discuss our reproductive health study of workers using video display terminals (VDTs). With me today is Dr. Theresa Schnorr, an epidemiologist on my staff and the senior project officer for this research effort and Dr. Gooloo Wunderlich, of the Office of Health Planning and Evaluation for the Public Health Service (PHS).

In May 1984, we testified before your subcommittee regarding NIOSH research on the health issues of VDT use. At that time, we indicated that we were planning to conduct a study investigating the effects of VDT use on reproductive health. I appreciate this opportunity to bring you up to date on our progress with this study.

We decided to conduct the study because of concern that VDT use may be hazardous to the reproductive health of women. Although several research efforts have looked at the possibility of an association between VDT use and adverse reproductive outcomes, none have resolved the issue; most have studied too few workers to enable scientists working in this area to have sufficient confidence in their findings. Given the limitations of these studies, we decided it was important for NIOSH to conduct a sound epidemiological study of a large number of working women using VDTs , including an appropriate comparison group. We expect this study will enable us to determine whether there is a relationship between VDT use and adverse reproductive outcomes.

NIOSH is in a unique position to conduct this type of study for two reasons: one, we have developed considerable expertise on the health effects of VDTs. We performed the first survey of ionizing and nonionizing radiation emissions from VDTs in 1977. We have conducted surveys, clinical, and laboratory studies to determine ergonomic and visual effects of VDT use, and to determine the effects of use on stress experienced by workers. Two, we have authority, given in the Occupational Safety and Health Act, to investigate occupational health problems. We are the only public health research organization legally empowered to enter the workplace and investigate working conditions and to access and review company records associated with these conditions.

We began looking for a possible study population for this research in 1982. In this search we consulted many potential user groups including international unions representing workers using VDTs ; State and Federal agencies; and industry groups. These included several potential study populations such as the insurance industry, airline reservation offices, the telecommunications industry, and the Social Security Administration. After more than two years of searching and evaluating potential study populations, we determined that the BellSouth and AT&T telecommunications companies at their facilities in the Southeast would give us the best scientific basis for success with this study.

We selected these study groups for several reasons. First, BellSouth employs a large number of female employees who spend most of their day working at VDTs. AT&T provides a large number of female employees who do similar work, without VDTs. The size of these two groups (2000 each)

provides a sufficient number of women of childbearing age to be able to detect a 50 percent or greater increased risk of miscarriages in the exposed group, if such a risk exists. This would be the largest human VDT reproductive study conducted to date. Also, personnel records are available for both worker groups and the method for studying the groups is logistically uncomplicated because the workers are located in a limited geographical area.

As is required for all major NIOSH research, the protocol for this study has received extensive peer review, conducted in public with the opportunity for public comment. The peer review group for this study consisted of six scientists, four of whom were from outside of NIOSH. These included three epidemiologists with expertise in reproductive studies, one statistician, and two experts in the areas of stress and ergonomics. In December 1984, we held an open meeting, announced in advance in the Federal Register, to peer review this study protocol. The meeting included representatives from the involved industry, including BellSouth and AT&T, and labor groups.

Based on the recommendations obtained as a result of the public peer review session, we revised the protocol and submitted it to the Human Subjects Review Board (HSRB). After receiving HSRB approval in May 1985, we submitted the protocol to the Office of Management and Budget (OMB) for its approval as required by the Paperwork Reduction Act of 1980 (Public Law 96-511). Under implementing regulations, "Controlling Paperwork Burden on

the Public" (5 CFR Part 1320), OMB must approve any Federally conducted or sponsored efforts to collect information on identical items from ten or more individuals or organizations. The phrase "collection of information" covers a wide variety of activities including among other items:

- o administrative forms and instructions developed for use as applications for benefits;
- o research protocols and instruments for the purpose of program evaluation;
- o data collection activities, periodic or single-time, to provide general purpose statistics
- o regulatory requirements that individuals or organizations report, disclose or maintain information;
- o management information systems and other means of gathering data for purposes of program planning or management; and
- o surveys to gather data for biomedical and behavioral research.

Prior to submission to the Department and OMB all proposals for information collection by PHS agencies are reviewed by the PHS Reports Clearance Officer, who is responsible for the policy, administrative, and technical aspects of the OMB approval process in PHS. These proposals are reviewed for technical quality, compliance with PHS, Department and OMB standards, policies and procedures and for consistency with Administration budget and management goals. Where appropriate, experts in statistical methodology and design or specialized program areas may be called upon to provide additional advisory reviews. Approval is granted on the basis of an assessment of the need for and intended uses of the information as well as the adequacy of the methodology and all other aspects of the total data collection plan.

A complete PHS project review includes many of the following specific areas which may apply to the particular case: protection of the privacy and confidentiality of respondents; paperwork burden on the public; practical utility; avoiding unnecessary duplication with other data collection activities; concurrences from agencies with related responsibilities; survey methodology and procedures; statistical standards; cost to respondents and to the Federal government; and the wording of documents addressed to the public, such as introductory statements, informed consent forms, etc.

As a general rule, the primary review by PHS is completed within 10 working days and the agency is contacted if issues are identified that require resolution. When needed, expedited reviews are completed within the day or overnight.

Section 3506 of the Paperwork Reduction Act requires that each Department designate a single senior official to carry out the responsibilities of the Department under the Act. In the Department of Health and Human Services (HHS), this designated official is the Assistant Secretary for Management and Budget (ASMB). All PHS requests for OMB approval must be submitted to the office of the ASMB for review and approval prior to submission to OMB.

An agency can appeal OMB's action to disapprove a specific request for clearance. Such an appeal must include new information and stronger justification to respond to OMB's reasons for disapproval.

With respect to the NIOSH VDT study, PHS approved the OMB clearance package on September 5, 1985, and forwarded it to the Office of the Assistant Secretary for Management and Budget for the Department, who subsequently forwarded it to OMB on September 27, 1985. In November, NIOSH and OMB were contacted in writing by BellSouth concerning questions they had regarding the study. In December 1985, OMB notified us that it had disapproved the study on grounds of methodological deficiencies, but indicated CDC had made a credible case for the conduct of a study.

In response to the concerns raised by OMB and BellSouth, we made several changes in the study protocol. We then sent the revised protocol to the original peer review panel and to the involved companies and labor unions for their further comment. The revised protocol responds to many of the concerns raised by BellSouth, and has now been resubmitted through CDC, PHS, and the Department to OMB, appealing its earlier action. A chronology of this study is attached.

We believe we have a scientifically sound study that will be valuable in evaluating this important public health issue. The peer review and HSRB review processes have provided us with extensive scientific review and the reviewers concur unanimously that the study should proceed.

This concludes my testimony. We will be glad to answer any questions.

CHRONOLOGY OF VDT REPRODUCTIVE STUDY

1982	NIOSH initiated feasibility assessment of whether a VDT reproductive study could be conducted and what populations were appropriate for study
1982 - May 1984	During this time period, several study designs were evaluated and abandoned
May 1984	Initial contacts with BellSouth, AT&T and other groups by NIOSH were made indicating intent to conduct a study and asking for demographic information about their VDT users so that an appropriate study population could be selected and a protocol could be developed
October 1984	Formal project (including a prospective and retrospective component) was approved by the Director, Division of Surveillance, Hazard Evaluations and Field Studies (DHSEFS), NIOSH
Oct. 1984 - Dec. 1984	Draft study protocol was developed which included retrospective and prospective components
December 1984	Peer and tripartite (management, labor and government) review of protocol was conducted at a public meeting
March 1985	Director, DSHEFS approved protocol
April 1985	DSHEFS submitted protocol to NIOSH Human Subjects Review Board (HSRB). At this point, the prospective component was determined to be questionable because of the plans by AT&T to switch to VDT use. However, the prospective component was left in the protocol as tentative
May 8, 1985	NIOSH HSRB approved project
July 1, 1985	NIOSH submits request for OMB clearance of this study pursuant to the Paperwork Reduction Act to CDC
July 11, 1985	CDC submits OMB package to PHS
August 19, 1985	Office of Management (OM) of PHS provided comments on the proposed study
August 27, 1985	NIOSH provided response to OM questions through the CDC and PHS Clearance Officers
September 5,1985	PHS submits OMB package to HHS
September 27, 1985	HHS submits OMB package to OMB.

64-893 O - 86 - 3

November 5-20, 1985	Correspondence received by NIOSH from BellSouth criticising the study protocol and indicating that NIOSH should not proceed
November 22, 1985	Letter from BellSouth to OMB asking for delay in OMB action. CDC notified of extension of the OMB comment period for this project
December 13, 1985	OMB disapproved VDT study. Notice of action was received in PHS on December 23, 1985
December 20, 1985	At the suggestion of OMB, meeting was held between BellSouth and NIOSH staff to discuss BellSouth's concerns with the protocol
January 1986	DSHEFS staff begin to revise protocol in response to OMB disapproval and first set of comments from BellSouth. (At this point a revised protocol also was sent to the peer and tripartite reviewers for their comments.)
January-February 1986	DSHEFS staff discussed the project with and provided information to Mark Weiner, the OMB statistician assigned to review the statistical aspects of the project. Discussions also were held with Faye Iudicello, the principal OMB reviewer
February 19, 1986	BellSouth submitted a second set of comments to NIOSH regarding the revised protocol.
March 7, 1986	NIOSH responded to BellSouth concerning their second set of comments.
March 12, 1986	NIOSH submitted the revised OMB submission to CDC
March 19, 1986	CDC submitted the revised OMB submission to PHS.
March 24, 1986	BellSouth contacted PHS to express their continuing concerns regarding the statistical design of the study and wanted PHS to review the latest comments being prepared by their statistical consultant
April 2, 1986	PHS received a letter from BellSouth along with the report of their statistical consultant dated February 12, 1986, and requested a meeting to discuss the statistical concerns
April 7, 1986	PHS received a letter from BellSouth transmitting a third series of comments from their consultants on the NIOSH revisions to the study
April 8, 1986	PHS staff provided CDC with comments on the resubmission and identified the issues that need to be addressed. Later in the day, PHS staff met with BellSouth

April 10, 1986	Conference call between PHS, CDC and NIOSH staff to go over questions concerning the project and how the resubmission package needs to be formulated
April 15, 1986	DSHEFS sent "draft" revisions to the revised OMB submission to CDC in accordance with the April 8-10 conversations (these revisions include the response to BellSouth's third set of comments).
April 17, 1986	CDC forwarded "draft" revisions to revised OMB submission to PHS.
April 21, 1986	PHS received revision of OMB submission from CDC. PHS staff called CDC to express preliminary concerns
April 28, 1986	PHS staff provided comments to DSHEFS via CDC about changing the revisions to the revised OMB submission.
May 12, 1986	"Final" revisions to the revised OMB submission forwarded to CDC by NIOSH.
May 13, 1986	"Final" revisions to the revised OMB submission forwarded by CDC to PHS.
May 19, 1986	Revised OMB submission forwarded by PHS to HHS
May 22, 1986	HHS sent revised OMB package to OMB.

Mr. GAYDOS. Let me ask one little practical question, Doctor. Could you do this study without including Bell?

Dr. MELIUS. At the present time we believe that BellSouth is the best study population we currently have available.

Mr. GAYDOS. What about the Pentagon and the Social Security Administration and other Government agencies? We have so many people. Maybe that is the place to go to get the material to study. Maybe there is some possibility or some substance to the fact they feel discriminated against; they are the only ones picked out. What do you say to that argument?

Dr. MELIUS. As I indicated in our testimony, we looked very extensively for other study populations, including Social Security and Government agencies. We did not just look in the private sector. We determined for a variety of reasons that BellSouth was the most appropriate group for this study.

Mr. GAYDOS. If it is going to come down to practicalities, whether we have a study or whether it is BellSouth, can you do a study without Bell?

Dr. MELIUS. At the present time we would really have to start all over.

Mr. GAYDOS. Let's answer the question, Doctor. Could you do a study without including those personnel in that particular corporate structure who wrote the letter to OMB?

Dr. MELIUS. As I said, I think that is the best population we could find to study.

Mr. GAYDOS. What is the second best?

Dr. MELIUS. I am not going to say there are not other possible study populations, but we feel on scientific grounds this was the best one to study and that is why we chose them.

Mr. GAYDOS. All good generals have an alternate. Where is your alternate?

Dr. MELIUS. At the present time we really do not have an alternate.

Mr. GAYDOS. I guess I pressed that far enough. Let me ask you about the cost. We are talking about costs. Do you think the costs are prohibitive? Do you think, in comparison to other requests you may or may not have made and your overall budgetary problems and in past dealings with OMB, the costs are a very important factor in this decision we have or do you think it is of minimal importance?

Dr. MELIUS. The cost has never been an issue in the review of the study, either internally or with outside reviews. We feel it is a reasonable cost for a study of this size and of this importance.

Mr. GAYDOS. If we may postulate, do you think OMB thought the cost was prohibitive or confiscatory?

Dr. MELIUS. They did not address that and never raised that in any of their concerns about the study.

Mr. GAYDOS. Let me leave one thought with you and that is that please consider some alternates in the meantime while we are doing some other things and take a look at some other groups, sources of information that you may want to study and, hopefully, get a comparative result from.

I will come back to you. At this time I would like to call on Mr. Murphy.

Mr. MURPHY. Thank you, Mr. Chairman.

To get back to the chairman's question of cost, OMB raises, of course, the objection based on the scientific objections. But we usually find OMB is more concerned with money than science or reason or other rationale.

What personnel are you going to use, your own in-house personnel or were you farming this out, this survey?

Dr. MELIUS. It would be a combination of our in-house personnel and some personnel in a contract, particularly for conducting the interviews.

Mr. MURPHY. I assume you had the contract before you submitted the proposal to the department; you had to have that all worked out. What was the contract cost?

Dr. MELIUS. We estimated the total cost for our study to be on the order of $360 to $400,000, in that range.

Mr. MURPHY. Was that the total cost of the study?

Dr. MELIUS. That was the total cost.

Mr. MURPHY. Postage, contract?

Dr. MELIUS. Contracting, for internal personnel over the two-year period of the study.

Mr. MURPHY. You are using internal personnel time devoted to that?

Dr. MELIUS. Yes.

Mr. MURPHY. So there are no other hidden costs. That was the package?

Dr. MELIUS. Correct.

Mr. MURPHY. What is your understanding of or do you have an understanding of what their scientific objections were?

Dr. MELIUS. Yes. They raised a series of four major objections to the study in their review. One was the concern about the sample size. Second was concern about how we defined the sample. Third was how we set variables in the study, how they were defined. And fourth was concern about some of the questions that were included in the study, whether those questions were relevant to the study design.

Mr. MURPHY. What were you asking?

Dr. MELIUS. We had a very extensive questionnaire asking about reproductive history, a few questions on stress involved with using VDT's as part of the workplace, and questions on medical history background.

Mr. MURPHY. Sex life?

Dr. MELIUS. Not directly, but certainly dealing with reproductive health questions. We must ask certain questions to deal with reproductive outcomes.

Mr. MURPHY. You are perhaps familiar with a movement in Congress to defund OMB's ability to have a regulatory review section. I see you smiling. Do I take it that you approve of that effort that is going on here, or do you think it has a proper function in Government?

Dr. MELIUS. I was not really aware of that movement nor am I really in a position to speak on OMB's function. The part we are dealing with was a law passed by Congress. It is a process we work through and work with.

Mr. MURPHY. To go back to costs and the tallying of the returns, was that to be handled by in-house personnel or was that under the contract too?

Dr. MELIUS. It actually would be a combination. I think Dr. Schnorr can probably address some of those questions more directly.

Dr. SCHNORR. Basically, the in-house personnel designed the study and will conduct the analysis. We plan to contract out the collection of information.

Mr. MURPHY. Thank you.

Thank you, Mr. Chairman.

Mr. GAYDOS. Before I call on Mr. Hayes, let me ask you a question, Doctor, or several. You got a peer review process, right? How do you choose these people? How does it work as a practical matter? For instance, this study, what did you do? Who did you contact? How do you select who you contact?

Dr. MELIUS. What we look for in that process are experts, some inside the Institute, most from outside the Institute who have expertise in the area of that study. In this case, we selected three epidemiologists who had expertise in the area of doing reproductive health studies. We also selected people with expertise in ergonomics and stress and who had done other studies on video displays. We picked a statistician to review the statistical design of the study.

Mr. GAYDOS. Are you satisfied no reasonable source could question the capabilities or qualifications of those you chose?

Dr. MELIUS. In doing scientific studies, one can always question the process, the design of the study, and so forth.

Mr. GAYDOS. The individuals, their credentials, are they of a top quality?

Dr. MELIUS. We believe they are of top quality.

Mr. GAYDOS. Stand up in comparison to what anybody else would choose? Is that a practical way of putting it?

Dr. MELIUS. I think it is very fair.

Mr. GAYDOS. Having done that, could you tell us it has great weight in your department within NIOSH, right? Once that choice is made based on their credentials, then you proceed on to take those individuals and say this is the sum total of their opinions and this is what we are going to do and this justifies us? Is that practically how it works?

Dr. MELIUS. Certainly. We carefully consult with them, get their input on the study, both in writing and in public peer review comments. In this particular study, we have now gone back to that peer review panel twice to obtain further input on some changes we made in the study, some concerns that were raised about the study design, some changes that occurred. So we work with them very extensively and take their comments with great concern.

Mr. GAYDOS. Taking that protocol to the OMB, then they told you what after you submitted this request for the study, the funding of it and you told them who is involved and here are their credentials and OMB did what? How did this justify their action? They said what?

Dr. MELIUS. They raised objections on the basis of methodologic flaws in the study.

Mr. GAYDOS. They questioned the people and their credentials?

Dr. MELIUS. Not directly. They questioned the study as it was submitted to OMB.

Mr. GAYDOS. They did not question those who you had consulted and those who made recommendations or their credentials as being experts in their field comparatively, but they did question the cost; is that it?

Dr. MELIUS. No. They raised questions about certain aspects of the design of the study and the methodology for the study.

Mr. GAYDOS. Those two things. And they are qualified to do that in your opinion?

Dr. MELIUS. I believe they can raise legitimate questions that we can respond to.

Mr. GAYDOS. Let me put it this way. Did they cite qualified and acceptable sources justifying their inquisition or inquiries?

Dr. MELIUS. Their response to us is a very short document and it does not cite a lot of factors.

Mr. GAYDOS. They did not take the time to say such and such an expert gave us this information and based on that we are questioning the need and necessity of your study? They did not say that? They just gave you a curt short statement saying that is it?

Dr. MELIUS. Correct.

Mr. GAYDOS. We are going to have them in. That is the reason I am setting this up. I want to read this record. We are going to have them in. We are going to let the public know. I have no control over the public. I represent a portion of it, and I am just going to get the facts out. Someone else is going to draw those conclusions.

I am asking you and you are telling me, you are spreading on the record here that this was their response after you had gone through the procedure which you outlined before and now you brought up to date, and then they concluded that they would not do it for reasons as stated.

Now I will ask you a question. If you want to answer it, fine. If you do not, I understand too.

Do you feel the staff at OMB is qualified to reject such studies—watch it—on scientific or technical grounds? You do not have to answer that question if you do not want to.

Dr. MELIUS. I do not think I am in a position to answer that.

Mr. GAYDOS. Let me ask you another little question. Are you satisfied that the revised VDT study protocol will provide you with the kinds of data you seek, the revised one?

Dr. MELIUS. As currently submitted to OMB review, we are satisfied with that protocol.

Mr. GAYDOS. If I may ask a question and you further revise and you went to other areas, would you still obtain the same data? I am talking about dealing with the Pentagon. There are a lot of VDT's down there. Maybe Social Security and other places?

Dr. MELIUS. If we went there, we would really have to reconsider how it would be done. I think, as I said, this was——

Mr. GAYDOS. Could be done though, couldn't it?

Dr. MELIUS. It is possible. There are problems with doing it. For example, in many Government offices and many other offices there are a lot of problems finding a comparison group that does similar work but does not use video display terminals. There are also prob-

lems with many types of office work where people use video display terminals very intermittently, a few hours a day. So when we looked for other populations, we had to keep all these factors in mind. I think that is a major consideration when looking for many kinds of office situations where, even though people use video display terminals, it is not very often and it involves everybody in the office, and we want to make sure we have both a study population that uses VDT's a large amount of their workday and can also find a similar population in that same office that does not use video display terminals. As you know, they are very common in almost all offices in this country now.

Mr. GAYDOS. As a layman, I find your explanation very difficult to accept. It is like fishing. You want to catch a 10 pounder. I would take the 5 pounder, later on catch a 10 pounder. You want the big fish, but we are looking for a study. We are looking for a direction. We do not have one.

Dr. Wunderlich, I am not going to let you get by without asking you a question. During the review process BellSouth was invited to come in and talk with reviewers after the protocol had been approved and the peer review had been approved as scientifically credible for NIOSH leadership. I imagine your leadership did approve it. Is this a standard procedure? Do you do it that way?

Dr. WUNDERLICH. We did not initiate the invitation to BellSouth. BellSouth called and asked to be heard and the clearance process is a public process. If anybody wants to come and express their views, they are welcome. We do not provide any written documents until it leaves the department and goes to OMB, but we do not mind hearing anybody. Instead of calling public hearings each time, which would slow down the process completely, if anybody wants to say anything, we hear them out. That does not mean that we do what they tell us to do.

Mr. GAYDOS. Do the public process comments appear at every level on a never-ending basis? How does that work?

Dr. WUNDERLICH. Under the Paperwork Reduction Act of 1980, which supersedes the Federal Reports Act of 1942, so this process has been going on for years gone by, the 1980 act has made more structure requirements of the review process and it requires an agency at a PHS level to do the review and have the assistant secretary or his designate approve it, and then it goes to the department level and there has to be a single senior official in the department who controls all of it. So I do it for the Assistant Secretary for Health or his designate, and he signs it, it goes to the Assistant Secretary for Management and Budget, and they approve it and send it to OMB.

In my office we do review all data collection activities from throughout the PHS—CDC, NIOSH, all of them—and we review it on technical grounds. We review it for methodology, procedures, content of the questionnaire and administrative and policy requirements before we send it. I think we do a thorough professional review, and it is reflected in the fact that very few of the PHS projects are disapproved by OMB. I would like none disapproved, but very few are disapproved.

Mr. GAYDOS. When did NIOSH refuse to participate? They said the record spoke for itself.

Dr. WUNDERLICH. Will you please repeat the question.

Mr. GAYDOS. Wasn't there a point in this process where NIOSH said we are not going to go in there and participate because the record speaks for itself, we don't have to?

Dr. WUNDERLICH. I am not sure what you are referring to, but it could be when BellSouth representatives wanted to come and talk to me. I indicated to them that I will not just meet with them without NIOSH and the parent agency, CDC, because I would like them to respond to BellSouth directly. However, at that time it was decided that NIOSH would not attend that meeting.

Mr. GAYDOS. In these communications with Bell, are they in writing or orally?

Dr. WUNDERLICH. BellSouth has sent me a letter——

Mr. GAYDOS. A letter?

Dr. WUNDERLICH. Yes, in which they had also attached their statistical consultant's comments, which I shared immediately with NIOSH and CDC, and it is in the record that was sent to OMB with our responses to it.

Mr. GAYDOS. Mr. Hayes from Illinois.

Mr. HAYES. Thank you, Mr. Chairman.

But I was content. You were going in the right direction, although the rights were not too positive.

Mr. GAYDOS. We did not catch the fish.

Mr. HAYES. I have a couple, three questions I might throw in. I got here a little late, and I want to apologize for it.

I take it, Doctor, that your study is still in progress; it is inconclusive at this point?

Dr. MELIUS. We are currently waiting for OMB review and action on the revised study protocol.

Mr. HAYES. Do you have a time schedule which you are operating under?

Dr. MELIUS. We believe we will get comments from OMB within the next few weeks, yes.

Mr. HAYES. Is that contingent upon additional funds to complete the study?

Dr. MELIUS. The funding is not a question at all. We need their approval to go ahead and get in the field and conduct the study, but the funding has really all been taken care of internally.

Mr. HAYES. That is all.

Thank you, Mr. Chairman.

Mr. GAYDOS. Doctor, could I identify this study as critical, something that really has to be done or based on what we had as far as the hearings in the prior couple years, and also your opinion based upon probably other comparable data that you have considered, is this very essential, really essential or just a study?

Dr. MELIUS. I think given the widespread concern about this issue, which we heard the Communications Workers speak to today—we certainly heard it in the previous hearings and we also hear it all the time from people calling with inquiries about this particular problem—given that widespread concern, given the widespread use of video display terminals, we think it is a very important study to do. That is why we are committed to doing it. We started planning several years ago and were committed to doing it at the hearing we had before your subcommittee.

Mr. GAYDOS. Do you think there is some evidence—forget about the quantity—there is some evidence that indicates that a study should be made, that there is a potential danger? Have you concluded that as a professional based upon information available to you? Maybe I should be asking your colleagues. You go ahead, respond to that.

Dr. MELIUS. I think there is certainly both concern and also a number of studies that raise the possibility of adverse reproductive outcomes from using video display terminals. The evidence is limited. The concern is widespread, and I think the concern is certainly a major driving force for us to do the study.

Mr. GAYDOS. You consider it very important, this request, and that this potential study be made?

Dr. MELIUS. Yes, we do.

Mr. GAYDOS. Any other comments from any of your other colleagues sitting at the witness table? Anything else you want to spread on the record we should know or we should consider as a committee?

Dr. SCHNORR. I would just like to point out that in our 2 years of planning for this study we looked at several industries, scores of companies and State and local record systems trying to identify the most appropriate study population and study design in which to address this question. Our current information indicates that the present study population is the only available one in which to conduct this study. There may be other study populations that could be appropriate, but it would require extensive effort to identify them, if they are present, and we feel that it is judicious to continue with the feasible study at this time.

Mr. GAYDOS. You are pretty solid in that opinion, that this is one of the outstanding and probably exclusive population areas that should be studied?

Dr. SCHNORR. We consider it an ideal population. The exposed and unexposed groups are very similar with respect to all factors except for the use of VDT's.

Mr. GAYDOS. All right. No further questions. I would like to ask you though if we have need of your documentation, written letters in your file, you will hear from the committee and I would like to have it made available if we consider it important enough. If you do not want to make it available, we will get it another way. We are going to ask you very nicely to make it available to us. We appreciate it and we may need them for other—counsel advises me he has enough already. [Laughter.]

There might be some other material we may need. Thank you very much for your appearance.

Mr. GAYDOS. This last group is the BellSouth Corp., represented by Hubert F. Owens, counsel, accompanied by Melissa Hess and Dr. Brian MacMahon.

Thank you for appearing. Without objection from my good friend Mr. Hayes, we will let your testimony become part of the record, and maybe we ought to get down to a good arm's length cross-examination because it seems that everything points toward this group as to why you are hesitant about allowing your population group or your employees to be subjected to some kind of a survey.

You continue on, make your presentation the best way you want to, but I will admit without objection into the record and so ordered it be made part of the record, that is, your submitted testimony.

STATEMENT OF HUBERT F. OWENS, COUNSEL, BELLSOUTH CORP., ACCOMPANIED BY MELISSA HESS, INDUSTRIAL ENGINEER; AND BRIAN MacMAHON, CHAIRMAN OF EPIDEMIOLOGY, HARVARD SCHOOL OF PUBLIC HEALTH

Mr. OWENS. Good morning, Mr. Chairman.

BellSouth Corp. is pleased to accept your kind invitation to present our position on the proposal by the National Institute for Occupational Safety and Health to study whether an association exists between employee exposure to video display terminals and an increased risk of adverse reproductive outcomes.

I am Hubert F. Owens, an attorney with the BellSouth legal department. I handle labor and other employment law matters. With me today is Melissa Hess, an industrial engineer for the company, and Dr. Brian MacMahon, chairman of epidemiology of the Harvard School of Public Health.

Due to an irreconciliable conflict in his schedule, Mr. Roy Howard, corporate director of labor relations to whom your invitation was initially extended, is unable to appear. I intend to acquaint you with the history of BellSouth's participation in this study and to detail our current position.

In your letter of invitation you indicated that the primary purpose of this hearing is to determine why NIOSH's VDT study has not been submitted to OMB for further review under the Paperwork Reduction Act. It is our understanding that the protocol, as amended, was forwarded to OMB on May 21st of this year. In that regard, we have sent a letter to OMB, with a copy to NIOSH, informing it of our intent to file comments on the latest protocol.

Mr. Chairman, BellSouth's continued interest in the NIOSH VDT study can be traced to several sources, not the least of which are its established corporate business goals. One corporate goal mandates our meeting the service needs of our telephone customers which entails, in part, the use of VDT's by our telephone operators. Another goal deals with human resources. Under that goal, BellSouth pledges, among other things, to maintain a safe work environment which is attuned to employees' concerns, health and well-being.

In keeping with the above-mentioned goals, we agreed to meet and cooperate with representatives of NIOSH to discuss a study designed to evaluate any association between VDT usage and adverse reproductive outcomes. In mid 1984, we were told that this study would involve VDT users from the government and include industries such as the airlines, banking operations, newspaper and insurance. Later in 1984, with the release of the first draft of the NIOSH protocol, we learned that a multi-industry study was not contemplated and that, even within the telecommunications industry, only the operator services employees in Southern Bell and South Central Bell would be used as study subjects. The control

group was determined to be AT&T operators who do not use VDTs and who work in the same geographic area.

Representatives of NIOSH have afforded BellSouth with ample opportunities to express our views on the proposed endeavor. While we continue to appreciate NIOSH's willingness to evaluate and respond to our views and concerns, there can be no denying that BellSouth's abundantly documented scientific concerns with the proposed protocol, in large measure, remain. I will elaborate upon those substantive concerns later in my testimony.

This subcommittee in its staff report "Oversight of OSHA with Respect to Video Display Terminals in the Work Place" concluded that there is not a plausible biological basis for believing that exposure to VDT's affect reproductive outcomes. However, we believe that a properly structured and authoritative scientific study can be justified on the basis of allaying user concerns, whether real or imagined, and as a contribution to a more informed utilization of VDT's by virtually every segment of the public and private sectors. With a resolve to never knowingly expose our employees to a work environment that would adversely affect their safety or health, we remain committed to the concept of a proper study irrespective of who performs that study.

We believe that all interested parties to this undertaking should share in the common objective of producing a scientifically sound and sufficient document that is worthy of acceptance and reliance. If the study methodology appears ill suited or unlikely to obtain that objective, then valuable resources may be wasted. Also, the level of apprehension of users, to the extent it exists, may be increased rather than dispelled. It is with the above-stated objective in mind that we have directed our efforts.

Early on we realized the need to go beyond our knowledge of and reaction to the proposed study and to that end we sought out those in the scientific community whose expertise was well recognized. Our search lead us to Dr. Brian MacMahon and his associate Dr. Sally Zierler of Brown University. These experts were asked by BellSouth in October 1985 to carefully analyze the most recent draft of the protocol and to advise us whether the design of the NIOSH study was capable of producing scientifically valid results. Thus, our position on the study would be primarily shaped by the expert opinions of Drs. MacMahon and Zierler.

Upon the receipt of their opinion, we advised NIOSH that our position on the protocol, as then structured, was that it could not produce scientifically valid results and that it would be unwise to undertake the study until and unless it was substantially modified. We assured NIOSH of our cooperation in such a task and provided them with Drs. MacMahon and Zierler's point-by-point critique. After NIOSH had filed its protocol with OMB in September 1985 we requested that it be withdrawn because it required substantial modifications. Upon NIOSH's refusal to withdraw the protocol, BellSouth informed OMB of our concerns with the protocol as reflected in the analysis of Drs. MacMahon and Zierler. In December 1985 OMB rejected the NIOSH protocol.

Another draft of the protocol dated December 1985 was reviewed by our experts and that critique was also supplied to NIOSH. While noting vast improvements in the protocol, our experts sug-

gested further changes in an effort to develop a protocol that would be strong, defensible and acceptable to all parties. During this period of time NIOSH and BellSouth maintained a dialog on the design and structure of the protocol and we continued to cooperate with the NIOSH investigators by permitting them access to personnel and employment records.

In February 1986 BellSouth received from NIOSH a further revised protocol. We were informed that the protocol would be submitted to OMB by the end of February. In fact, it was not submitted until May 21. We received a copy of the NIOSH submission to OMB on May 27 and confirmed that the protocol submitted was essentially the same as that dated February 1986.

Drs. MacMahon and Zierler had previously provided us with a critique of the February 1986 protocol. Although there are changes in the current submission, the overall concerns remain the same. Their scientific concerns are in the following areas: one, inadequate provision for evaluation of recall bias; two, retention of substantial components of the questionnaire which are useless to the objectives of the study as stated, are an imposition on the study subjects' time, and constitute additions to the cost of data collection, processing and analysis; retention of questions that are unnecessarily intrusive given the stated objectives of the study is the third concern; and the fourth, inadequate consideration of alternative study designs.

Considering Drs. MacMahon and Zierler's views, and NIOSH's unwillingness to incorporate recommended substantive changes in the protocol, BellSouth advised the Department of HHS, Health and Human Services, of our position on the study.

In our letter to HHS, we pointed out that it was not BellSouth's goal to prevent NIOSH from studying this subject or from relying, at least in part, on BellSouth employees for its study subjects. Rather, we emphasized our insistence that any study be capable of achieving the intended results of proving or disproving an association between VDT usage and adverse reproductive outcomes. We noted that further changes in the design of the study needed to be made. As an example, we suggested the use of a case control study based on a multi-industry review of medical records. Moreover, BellSouth committed to immediately join NIOSH in a review of the medical and insurance records of BellSouth employees to test the feasibility of this approach. NIOSH has rejected our above-outlined suggestions and offers.

We believe that the proposed protocol is lacking in two major considerations. As earlier stated, from a scientific viewpoint we conclude that the data generated will not be substantive enough to state if there is or is not an adverse relationship between VDT usage and pregnancy outcomes. From a perceptional viewpoint, the study is too narrowly defined in that it only includes telecommunications workers. Therefore, other industries which are equally as VDT intensive, and the public at large, will not give significant credence to the findings nor deem them applicable to their utilization of VDT's.

In conclusion, BellSouth considers it our obligation as an involved and affected corporate citizen to work to achieve a properly structured inquiry whose results will be reliable and meaningful.

That is to say, the importance of the undertaking demands the best study vehicle or mechanism possible. However, in spite of our reservations, we will continue to support the concept of such a study.

Thank you, Mr. Chairman, for affording BellSouth with the opportunity to state our position in this matter. We are available for questions.

Mr. GAYDOS. Counsel, you heard the testimony before, that is, that Bell constituted the ideal population group. You are questioning that conclusion. I think, as I understand your testimony, you want others included. You outlined the conditions. You are then taking a position that that conclusion by the witnesses before this committee is erroneous or not true; is that right?

Mr. OWENS. No, sir; I am not taking that position nor have we ever accused anyone of an untruth.

Mr. GAYDOS. Are you an ideal population group?

Doctor, you might want to respond. You are the expert that has been retained.

Dr. MACMAHON. Yes.

Mr. OWENS. We have two perceptions: one is scientific, as I stated; the other is the perception of those who will be affected by the study and those are employees and employers. All we say from that point of view, not the scientific basis, is that if you choose one industry and one segment of the nation in an effort to do a national study under the mandate of this Congress, there are those who will say that is not indicative of my work place. We were told when we volunteered to begin this study 2 years ago—and I have been involved with it at least that long—that we would participate. We cannot tell you why other companies did or did not, but we are still participating and we intend to continue. But we are saying that someone should think about the perception of the public to a narrowly gauged study. That is all we ask. And I am sorry to put that—I can handle that part of it, but Dr. MacMahon can tell you about the scientific aspect.

Mr. GAYDOS. I find no serious question with your logic and with your position. It is very difficult to argue against what you have to say, particularly though it might be self-serving to some extent. All of us are, understand that. But I see some logic to your position and conclusions you reached.

I am asking, if I may—Doctor, I probably should have directed it to you—the conclusion we had from our witnesses, other experts in the field, they concluded that this Bell was the ideal population group. Could you address yourself to that statement. Is that true, false or is it just a self-serving declaration?

Dr. MACMAHON. I think it is an exaggeration. I think it is a good population group to study, but one of my concerns—pardon me. I will go back. It does have the characteristics that the NIOSH people described, that you have two groups that are very comparable, except one uses VDT's and the other does not. It has problems. For example, one of the groups is on strike right now. The other is not. What difference, if any, is that going to make on the respondents' answers to the questions? So I would not call it an ideal group.

I think it is a good group, but one of my major concerns about the study is sample size, whether the group is large enough. There

are approximately 2,000 women in each group and they are estimated to give about 500 or produce about 500 pregnancies over the study period. I think we are agreed with NIOSH—I think NIOSH agrees with the point—that the only reproductive outcomes that can be evaluated with sufficient statistical power are the frequency of spontaneous abortions and the frequency of all congenital malformations taken as a group.

This last group, all malformations, makes no biological sense. There is no substance that we know that increases all malformations as a group. One has to look at individual malformations, and this cannot be done on this population size.

So while I think this is a good population, I do think it needs to be expanded.

Mr. GAYDOS. Are you saying, if I may as a layman try to interpret what you are saying, that there is a good possibility that this group might have, for instance, a group of workers that are prone because of genetic problems to have malformed children, maybe premature, abortions and that if it is studied in that respect it is not going to be a true study as something caused by the VDTs? Is that what you are saying? There is an added element?

Dr. MACMAHON. No.

Mr. GAYDOS. You are saying biological and things of that nature, and you are getting me all confused. This record has to be read by laymen and by legislators who are not experts like you, and I hope you might bear with us and try to put it in layman's language, if you could, so I can understand it. I am not the smartest fellow; I am not the dumbest. I am in the middle somewhere. Am I stating it correctly?

Mr. HAYES. Yes, you mentioned about the strike. I want to deal with that later.

Mr. GAYDOS. Let me ask you a question, Doctor, in response to my question, if I might get you on the track, if that is acceptable to us. I say this with all due respect to you. Let me ask you this question. If not your population group, whose then? Is that what the problem is? Generally throughout the industry or other industries? Is that what you are saying?

Dr. MACMAHON. NIOSH has——

Mr. GAYDOS. They have said before us that your population is ideal, and they want to make the study there. You are taking a position, for reasons that I understand, that you do not want to be the only one and maybe I would feel the same way, I do not know, but I am trying to find out can we have a study, an effective, good, accurate study by dealing with a population group other than yourself? Maybe that is the way to put it. I do not know.

Dr. MACMAHON. Mr. Chairman, please do not refer to it as mine.

Mr. GAYDOS. I mean not yours, Bell's. It should be yours; you are employed by them. You should consider it yours.

Dr. MACMAHON. As a citizen and telephone ratepayer, I think it is equally in the interests of BellSouth to have a good study done as it is to the CWA, and I think BellSouth is of that opinion too. But what I have addressed myself to is simply the question of: Is what is being proposed a good study? And I do not think it is.

Mr. GAYDOS. Why?

Dr. MACMAHON. The one issue I have addressed is sample size. It is too small.

Second, there is inadequate provision for what is sometimes called response bias or recall bias. It has been shown on several occasions, for example, that people living near a toxic waste site report more symptoms of every kind than people who do not, even though there is no contamination from that waste site. If you think you are exposed to something, you try to think, well, what could that thing be causing.

Now, the original NIOSH protocol made this situation worse, not as a fault of the investigators but the fault of the Human Subjects Review Board which insisted the opening letter said something like we are doing a study of the adverse reproductive effects of VDTs, which immediately plants in the subject's mind——

Mr. GAYDOS. That would be a deficiency. We always have a percentage of error in those studies, and we take those elements into consideration. That would be true in any type of study you would make.

Dr. MACMAHON. Yes.

Mr. GAYDOS. We would have to throw the study out with the bath water and never use it again, because it always will have that deficiency. Isn't that true?

Dr. MACMAHON. That is true, but there are ways of evaluating it. One of those would be as we have suggested and which NIOSH has declined, to look at the medical records of women who report normal pregnancies, not because of that normal pregnancy but because the record of that normal pregnancy will tell you whether she had abortions, spontaneous or induced, prior to that pregnancy which could then be compared with what she tells the interviewer over the phone. The NIOSH investigators appear not to have understood, at least in the latest version, appear not to have understood what we are trying to say in this. It is not that we are trying to get a total assessment of all early abortions. That is not possible. But what we are trying to ascertain in suggesting that is to find out whether there is equal discrepancy in the exposed group and the nonexposed group, and NIOSH has dug its toes in on that issue and will not examine the sample.

I am sorry. The latest position is that if they find an association between abortion and VDT use, then they would consider that; but the difficulty is that it is going to take a year or two to do that after they found the association, and the procedure could equally well be incorporated in the study as beginning.

Mr. GAYDOS. Aren't you arguing the methodology among two experts, including yourself and NIOSH?

Dr. MACMAHON. Yes. I am simply stating my position.

Mr. GAYDOS. Would that be justification to be contrary to the study, to fight the study, to question it, because you have a difference in methodology or expert approach to each of your conclusions? We are always going to have that, aren't we, disagreement between experts? They say if you put a couple lawyers in a room you never get an ultimate disposition of the problem you have. So the same among experts, I have to presume.

Dr. MACMAHON. Yes. That is the situation. I should say, incidentally, that the cost of the study as given by NIOSH is not $360,000.

Given in their submission to OMB it is $449,000, and I think for $449,000 you should get a pretty good study. I do not think they have one. That is an opinion.

Mr. GAYDOS. In other words, you are spreading on the record your expert opinion that for the amount of money, the cost and the limited group, that the study would be suspect as far as getting the most bang out of your dollar; is that it?

Dr. MACMAHON. It could be done very much more cheaply if a lot of what I consider frankly to be garbage in the questionnaire were eliminated. Questions such as: Is it true or false it sometimes gets too hot at work? Things are sometimes pretty disorganized, true or false? Nobody works too hard, true or false? There are 60 questions of that nature, and there is a whole bunch of questions which I feel are intrusive, asking about all husband's birth dates, whether they have a vasectomy, detailed histories of contraceptive use not related to any pregnancies but between pregnancies which are there only to address the question of fertility, which is a nonissue as far as I am concerned. There has never been any suggestion or question that infertility is a problem with VDT users.

Mr. GAYDOS. When raising those questions as to the nature of the questions to be propounded, you would then take the position if that question in the questionnaire was used in any other work population group it would be improper also; is that what you are saying?

Dr. MACMAHON. Yes, sir.

Mr. GAYDOS. Not just because it is your people or your immediate employer, Bell, but other groups, these questions would be of no significance or improper or nonconclusive and just should be stricken; is that what you are saying as an expert?

Dr. MACMAHON. I say that about half of this questionnaire is either irrelevant or intrusive or both.

Mr. GAYDOS. All right. If there were changes made in the area of questions, where the legitimacy of your complaints would be responded to, would that have a possibility of influencing your ultimate decision in the matter? I am talking about the nature of the questions. What other problems do you have with this proposed study besides the nature of the questions and, No. 2, the costs and what you get for the costs? Those are the two things you have raised so far. What other questions would you have?

Dr. MACMAHON. Just the one of sample size. The sample is too small. The questionnaire is too long.

Mr. GAYDOS. If the sample group would be enlarged, so the group would include other people, if that would occur, then do you have any other questions?

Dr. MACMAHON. No. Basically three: the sample size were increased, the questionnaire reduced and provision made for evaluating whether the two groups are giving you information of comparable completeness.

Mr. GAYDOS. How big or how large should the sample be? How much enlargement would be acceptable to you as part of the sampling of the population groups?

Dr. MACMAHON. I do not think there is any answer to that, but I would like to be able to look at outcomes other than spontaneous

abortion, and I believe that one would need a sample size three or four times this to do that.

Mr. GAYDOS. And your question is not primarily because the proposed study is only limited to Bell; you just want more——

Dr. MACMAHON. Bell would be a good component of such a study.

Mr. GAYDOS. A component?

Dr. MACMAHON. Yes.

Mr. GAYDOS. What about the cost? You said it is 400 some odd thousand dollars. Do you think that is sufficient as far as the results that you could expect or do you think that figure is high or low?

Dr. MACMAHON. I think it is atrocious.

Mr. GAYDOS. Atrociously high?

Dr. MACMAHON. Yes. Eighty dollars per subject for a telephone interview and to look at some medical records, I think it is out of this world. I do not say it won't cost that. It may be because the questionnaire is so long; but if you half the length of the questionnaire, then it could be done much cheaper. You could get a double size population for not quite the same money.

Mr. GAYDOS. In other words, spend the same 400,000 plus and get twice as much of a grouping, because you would cut the questionnaire down?

Dr. MACMAHON. Yes.

Mr. GAYDOS. And you would have a better sample size, amalgamation of employees, not just from Bell?

Dr. MACMAHON. Yes, because the generalization issue is whether what you find in the telephone company would apply elsewhere.

Mr. GAYDOS. Let me ask you some general questions. Is it the proper approach in your professional opinion that is being made to this problem, given the criticisms you have and if they were to be corrected, in your professional opinion would it be the proper approach to this problem, making a study like that to see what the results are? And if it is not, what would you suggest in place of it?

Dr. MACMAHON. The difficulty is, as the NIOSH people have said, they have looked for other populations. I would much prefer a study that were based entirely on records; that is, you got the record of whether the individual worked with a VDT, whether her work was such she was exposed to VDT's and you had a record of whether or not she had a spontaneous abortion. Now, I cannot say that there are populations where those two items are available and can be computer linked or hand linked in any way. As NIOSH has indicated, they have spent a lot of time looking and not finding one, but I suspect—I am not sure about this, but judging from their mission I suspect that their search has been industry oriented, occupation oriented, and I wonder whether there are not such populations, for example, in New York State where the reporting of all fetal deaths is required on fetal death certificates, whether one could not find some population there, start with a population of abortions and some kind of control group and look at occupational records.

The frequency of VDT use now, as the CWA representative said, is so high that I believe a case control approach rather than this interview approach—that the record approach might be feasible. I

cannot say that definitely because I have not put in the time to work out all the bugs.

Mr. GAYDOS. Can you tell the committee on the record whether or not the position you just stated is accepted in other professional circles among your peers that feel the same way as you, that you are not just stating something that is so unorthodox, you know?

Dr. MACMAHON. On this issue of VDT's?

Mr. GAYDOS. Is there a division in the expert field as to what you are saying?

Dr. MACMAHON. I do not think this issue has been widely discussed in the expert field, but on the issue of are you better off getting information from records than by asking subjects, than asking a person, I do not think there is any question about that, but that would be widely accepted.

Mr. GAYDOS. That is what I am talking about, the method that you are espousing. I am talking about how you take this study and where do you go and how to do it mechanically. Am I correct in assuming what you tell me is a position that exists in the professional field? That is all I am asking you. You are not the only one that advocates that; there are other professionals who feel like this?

Dr. MACMAHON. I would think everybody would feel like that.

Mr. GAYDOS. Apparently they do not because we have some other people not——

Dr. MACMAHON. It depends how far you want to generalize. I am not talking specifically about the VDT issue. I am saying in general if there are things that are recorded you are much better off relying on the records than asking the individual as to whether that happened to them or not.

Mr. GAYDOS. I was just wondering if that was the accepted position among you experts in this respect. Anything you say probably can be argued against by another expert. You know, you feel this is the way to go. He says, no, this is the way. I can understand that. I am just asking, is that a viable or is that a generally accepted proposition that you can go that way and it is accepted among your peers, that you could go that way? It might be a division of philosophy.

Dr. MACMAHON. I do not think so, except in the situation where you are not sure everything is recorded; but if you are sure that something would be recorded, then I do not think there would be any question about it.

Mr. OWENS. Mr. Chairman, may I inject one statement here. I think I am compelled to say on behalf of my client that our purpose in retaining a gentleman of this expertise was to take his recommendations obviously, however they came. We could not presuppose with all of our knowledge in our other fields; this being a scientific endeavor, we thought we owed it to our employees and to our company to make certain in our opinion in cooperation with NIOSH that we all moved towards a common objective.

And also I commend the committee for its concern. The fact is that since November 1985, and we are now in June, we have on the public record in each instance voiced scientific concerns and that has been the extent of it. Obviously, they have had some credence because they have been accepted. We have had a good relation, in

our opinion, with NIOSH. The mere fact that in late 1985 and 1986 in a matter that began in 1982 insofar as this committee is concerned, we do not feel there has been any unreasonable delay, and certainly we have not attempted to squelch anything in this regard. People should keep in mind that the laws of the United States provide this agency may come in to our establishment at any time it chooses and conduct whatever investigation it chooses.

So the idea that we, through scientific inquiry and exchanging of ideas, have attempted to squash this is, to us, insulting to our integrity. So we feel that we have made great strides and progress in a brief period of time. November of 1985 was the first dialog between MacMahon's group and the equally competent people at NIOSH. By the way, he is also a consultant to NIOSH. I do not see any diametrically opposing types of views, but rather a group of scientists moving into an area where there is very little knowledge, agreeing there is a need for more knowledge, attempting to get the best study vehicle possible; and we stand by our initial proposition that that is in the public good. It is good for us and good for our employees.

So we do not apologize for our concern, and we hope that we have made a contribution to the progress and we will continue to cooperate with this study, with our employees, in an effort to move this thing along because the longer it stays and the more people, whether informed or otherwise who express concerns, it has an effect upon those people who use it and we think that more knowledge is required. To that extent we have welcomed the opportunity to participate and we will continue to participate.

Mr. GAYDOS. I have to ask you this question. I was going to ask it and I am going to ask it right now. Was it ever your intent to delay or stop this study? Maybe I will help you out a little bit and say in its present form.

Mr. OWENS. From November of 1985 till this point in time, our purpose has been to have this study structured in such a way that it will achieve the results that all hope it will. We happen to believe that there is not going to be a product that is going to show that there is a health risk out there, but that still remains to be determined by those who are experts.

No, if you are asking me by asking them to pull back the study and rewrite it in a period of three weeks, if that is characterized as delay, then we say, yes, we believe that kind of delay is justified.

Mr. GAYDOS. Assuming some of these things we are talking about is correct, they change the questions, they eliminate say 50 percent of those questions there, they enlarge the group somewhat, then would you be in a position as a corporate structure to say, all right, we are included in the group, go ahead and go?

Mr. OWENS. Yes.

Mr. GAYDOS. You would?

Mr. OWENS. Yes. We have never said not to go. We have said the best way to go in our opinion, but we realize that it is ultimately NIOSH's responsibility to make its own determinations and to obey its own statutory mandates. But when we are the only subject and we are a conscientious, cooperative citizen, there is nothing wrong with us working together.

Mr. GAYDOS. That is very clear.

Mr. Hayes, I call on you until I get my other questions in line.
Mr. Hayes.

Mr. HAYES. Thank you, Mr. Chairman.

I will admit my lack of knowledge on the issue. I will do that up front. I am trying to get this in focus, in what I would categorize as lay terms. Counsel, I know it is hard for you to do. I want to see if I have drawn the wrong conclusions based on your testimony, as I understand it.

Your client, BellSouth, has not concluded that the NIOSH study is unnecessary, have they?

Mr. OWENS. No, sir.

Mr. HAYES. What are you saying? That the ground rules should be changed and broadened to include others? Is that what you are saying?

Mr. OWENS. We are saying that that should be looked at and not rejected as it has been to this point in time. We are saying that there is a legitimate, if you will—I also am equally dense on the scientific. We did not presuppose we could go out and make a critique of an agency with the expertise of NIOSH. That is why we asked someone who is expert in the field. So I do not feel embarrassed. There are a lot of things I do not know, Mr. Hayes, but we believe the study should be done and we are perfectly content with NIOSH doing it and our work place will be their work place.

Mr. GAYDOS. Charley, yield to me?

Mr. HAYES. Yes.

Mr. GAYDOS. If you are so intent, did you so inform the Budget Office or was your information to the contrary?

Mr. OWENS. My information is a matter of public record. The copy of our letter to OMB went to NIOSH. Every communication we have had, HHS——

Mr. GAYDOS. On the record you never stated that to the Office of Management and Budget, that you were, before it was changed? You said that in a letter?

Mr. OWENS. Yes, sir. We have a copy of it and we will be glad to furnish it. We have said that in every letter including a request made of us by the Director of NIOSH after the rejection in December. We had asked for a meeting and we even informed them of the rejection because we just found out about it. He said in light of that would we continue to cooperate, and I have a letter from Roy Howard, which we will be pleased to produce, where we said from the beginning we will cooperate and we will continue to cooperate. The last sentence in the letter—well, this is to Dr. Wunderlich, the last communication we had with HHS or NIOSH. We again say the same thing. We have been saying from the beginning that BellSouth strongly supports the need for developing sound scientific information on this subject. We believe it is incumbent upon NIOSH, however, to proceed deliberately and to pursue research capable of producing more useful reports than could come from its proposed study.

I can get a copy of our letter to OMB as recognized by NIOSH, and I am sure as known by all members of this committee, that our comments as filed in the record are our right under the particular procedures. So I hope no one has mistakenly taken our right to comment in a three-page letter as something improper or intrusive

into the affairs of some agency. As to how agencies conduct their business is a matter of their concern, and we have faith in the process.

So we say that from November to this date in light of the magnitude of this, the importance of this subject, that the pause, if you will, that has been undertaken by NIOSH at our request and at our insistence has not been contrary to the best interests of this study or those who are out there using it. The Government is the largest user. Everybody wants to have an answer to this question, but it deserves the best scientific effort that this Nation can mount or we are going to add garbage out there when we should have something that is reliable, Mr. Chairman, and I know that is what you want too.

Mr. GAYDOS. Thanks.

Mr. HAYES. I was particularly glad to hear you say, counsel, your interest and concern for the employees is one of the reasons for this kind of study. I hope you can convey that by way of a side line to AT&T. You know, they ought to be concerned about their employees, hence the strike may not last so long.

Mr. OWENS. I think AT&T is capable of handling its own affairs. I want to say something for CWA. We share in their conclusions. We obviously do not share in some of their other remarks, but we have a fine relationship with CWA in the matter of quality of work life. We are proud of what goes on in this regard, over 400 committees of employees and managers who meet on a variety of subjects, including VDT's, seating and lighting and things like that, and we are going to continue to do that. So we are going to continue to do that. We are quite proud of the fact that we have a record independent of this that shows we work with this union in a matter of making certain that the work place is not only the most productive but healthful and safe and those type of things. That is a part of our Bell System heritage and we do not intend to abandon that kind of history.

Mr. HAYES. Another side line. Long strikes, you know, sometimes are conducive for population expansion, you know that.

Mr. OWENS. Yes, sir. [Laughter.]

Mr. HAYES. Thank you, Mr. Chairman.

Mr. GAYDOS. Have you had discussions along this line with the Communications Workers during the last 6 months or 9 months on this so-called controversial position that you find yourselves in? Have you talked this over with the union, as pursuant to the collective bargaining agreement where you should?

Mr. OWENS. We will start bargaining with CWA in 2 weeks on our contract. I believe Mr. Howard knows these people and we have exchanged views as to whether or not we agree in the proper approach to this subject. I think there may be some disagreement, but I think there have been—I have not talked with the lady and the gentleman here.

Mr. GAYDOS. As counsel, you would know whether you have had arm's length discussions and maybe some special hearings or discussions. What is the general situation as far as your communications with the Communications Workers? Is it pretty good in your estimation or so so?

Mr. OWENS. I think our labor relations history is admirable. The representatives of CWA here are out of Washington or what we refer to as the international national office. We deal with District No. 3 and it has a president and it has a hierarchy of officers, and we meet daily on a whole host of subjects. But I have not personally talked to the lady or to the gentleman on this subject. I am sure that at some of these meetings we have been to, for example, in Cincinnati there has been some talk in the hall, but I cannot answer your question is what I am saying.

Mr. GAYDOS. Let me ask it this way. The position that you take, has it ever been discussed with the Communications Workers as to the position you take as far as being adverse to this study in its present form? Let me put that caveat on it.

Mr. OWENS. Not by me. I will say that everything I have said here today in a much better fashion is in the form of some document to Dr. Wunderlich, to the various agencies that had a part in this. We said it differently, depending on who was looking at it, but our position is—we submit that an objective analysis will show it is consistent. I think they have had the opportunity to obtain copies of the documents that we have filed with the agencies. They are not privileged. But in terms of me sitting down and talking to them, I have not.

Mr. GAYDOS. It bothers me that on a subject so sensitive, involving so many workers and on a very important subject matter, there would not be, you know, more of an exchange in a concert of activity between you and the union as far as your position, what position you intend to take, and maybe some of the differences could you have worked on, because you are dealing with a very sensitive subject; and I think that goes, as you mentioned, to the overall type of a situation that exists communicatively between you and the union. If you are closely operating together, I would think that your position would have been one of unanimity rather than difference at this time.

Mr. OWENS. I totally agree that whatever the level of communication before it has not been satisfactory because, obviously, there are differences and I am sure that I can speak for Mr. Howard and those who do these things on a daily basis and say we should get closer together on this. I think we can always work out these concerns. It is just a question of due deliberate speed and how you find that. But I would pledge in behalf of BellSouth to doing a better job of communicating with CWA on a matter of mutual concern, of importance to both of us.

Mr. GAYDOS. I am glad to hear that, and I just want to voice my own personal opinion at this time that the differences do not seem to be insurmountable. There are areas of compromise that may occur. We are going to take a look at it. We are going to have to make a decision as to what our communication should be with the Office of Management and Budget and whether we should communicate with them. We probably will in some fashion. As to what the contents will be, it will probably be open for discussion. We will work it out.

Again, I want to emphasize the fact I was expecting more of an antagonistic position from you. I really was, based upon advanced items at my disposal, and to me it seems that things might be able

to be worked out hopefully along a line that would be satisfactory to all parties involved and for the ultimate ulterior motive, ultimate exclusive motive, to get a study done on this very important problem.

I want to thank you for your candid remarks. You did not hold back anything, and the committee is very, very grateful. I am very happy with the hearing today because I think everybody followed that procedure. Hopefully we can work something out to the committee's satisfaction. I want to congratulate you for participating in the committee's business because it is the only way we can solve this problem. Thank you very much for appearing.

Let me at this time call a halt to things, and we have no other further hearings scheduled on this matter unless it is decided we hold it; and until the call of the chair, the committee will stand adjourned.

[Whereupon, at 11:18 a.m., the subcommittee was adjourned to the call of the chair.]

[Prepared statement of Hubert F. Owens and additional material follow:]

PREPARED STATEMENT OF HUBERT F. OWENS, COUNSEL, BELLSOUTH CORP.

The BellSouth Corporation is pleased to accept your kind invitation to present our position on the proposal by the National Institute for Occupational Safety and Health (NIOSH) to study whether an association exists between employee exposure to video display terminals (VDT's) and an increased risk of adverse reproductive outcomes. I am Hubert F. Owens, and my position is that of an attorney in the BellSouth Legal Department. I handle labor and employment law matters. With me today is Melinda Ross, an Industrial Engineer for the Company and Dr. Brian MacMahon, Chairman of Epidemiology of the Harvard School of Public Health. Due to an irreconcilliable conflict in his schedule, Mr. Roy Howard, Corporate Director of Labor Relations to whom your invitation was initially extended, is unable to appear. I intend to acquaint you with the history of BellSouth's participation in this study and detail our current position. In your letter of invitation you indicated that the primary purpose of this hearing is to determine why NIOSH's VDT study has not been submitted to the Office of Management and Budget (OMB) for further review under the Paperwork Reduction Act. It is our understanding that the protocol, as amended, was forwarded to OMB on May 21, 1986. In that regard, we have sent a letter to OMB, with a copy to NIOSH, informing it of our intent to file comments on the latest protocol.

Mr. Chairman, BellSouth's continued interest in the NIOSH VDT study can be traced to several sources not the least of which are it's established corporate business goals. One corporate goal mandates our meeting the service needs of our telephone customers which entails, in part, the use of VDT's by our telephone operators. Another goal deals with human resources. Under that goal, BellSouth pledges, among other things, to maintain a safe work environment which is attuned to employees' concerns, health and well-being.

In keeping with the above-mentioned goals, we agreed to meet and cooperate with representatives of NIOSH to discuss a study designed to evaluate any association between VDT usage and adverse reproductive outcomes. In mid-1984, we were told that this study would involve VDT users from the government and include industries such as the airlines, banking operations, newspaper and insurance. Later in 1984, with the release of the first draft of the NIOSH protocol, we learned that a multi-industry study was not contemplated and that, even within the telecommunications industry, only the operator services employees in Southern Bell and South Central Bell would be used as study subjects. The control group was determined to be AT&T operators who do not use VDT's and who work in the same geographic area.

Representatives of NIOSH have afforded BellSouth with ample opportunities to express our views on the proposed endeavor. While we continue to appreciate NIOSH's willingness to evaluate and respond to our views and concerns, there can be no denying that BellSouth's

abundantly documented scientific concerns with the proposed protocol, in large measure, remain. I will elaborate upon these substantive concerns later in my testimony.

This subcommittee in its staff report "Oversight of OSHA With Respect to Video Display Terminals In The Workplace" concluded that there is not a plausible biological basis for believing that exposure to VDT's affect reproductive outcomes[1]. However, we believe that a properly structured and authoritative scientific study can be justified on the basis of allaying user-concerns, whether real or imagined, and as a contribution to a more informed utilization of VDT's by virtually every segment of the public and private sectors. With a resolve to never knowingly expose our employees to a work environment that would adversely affect their safety or health, we remain committed to the concept of a proper study irrespective of who performs that study.

We believe that all interested parties to this undertaking should share in the common objective of producing a scientifically sound and sufficient document that is worthy of acceptance and reliance. If the study methodology appears ill-suited or unlikely to obtain that objective, then valuable resources may be wasted. Also, the level of apprehension of users, to the extent it exists, may be increased rather than dispelled. It is with the above-stated objective in mind that we have directed our efforts.

Early on we realized the need to go beyond our knowledge of and reaction to the proposed study and to that end we sought out those in the scientific community whose expertise was well-recognized. Our search lead us to Dr. Brian MacMahon and his associate Dr. Sally Zierler of Brown University. These experts were asked by BellSouth in October, 1985 to carefully analyze the most recent draft of the protocol and to advise us whether the design of the NIOSH study was capable of producing scientifically valid results. Thus, our position on the study would be primarily shaped by the expert opinions of Drs. MacMahon and Zierler. Upon receipt of their opinion we advised NIOSH that our position on the protocol, as then structured, was that it could not produce scientifically valid results and that it would be unwise to undertake the study until and unless it was substantially modified. We assured NIOSH of our cooperation in such a task and provided them with Dr. MacMahon and Zierler's point-by-point critique. After NIOSH had filed its protocol with OMB in September, 1985, we requested that it be withdrawn because it required substantial modifications. Upon NIOSH's refusal to withdraw the protocol, BellSouth informed OMB of our concerns with the protocol as reflected in the analysis of Drs. MacMahon and Zierler. In December, 1985 OMB rejected the NIOSH protocol.

Another draft of the protocol dated December, 1985 was reviewed by our experts and that critique was also supplied to NIOSH. While noting vast improvements in the protocol, our experts suggested further changes in an effort to develop a protocol that would be strong, defensible and acceptable to all parties. During this period of time NIOSH and BellSouth maintained a dialogue on the design and

[1] See, e.g., "Oversight of OSHA With Respect to Video Display Terminals In The Workplace", Subcommittee on Health and Safety, Committee on Education and Labor, House of Representatives, August 1985 at 12-13, 28-29.

structure of the protocol and we continued to cooperate with the NIOSH investigators by permitting them access to personnel and employment records.

In February, 1986, BellSouth received from NIOSH a further revised protocol. We were informed that the protocol would be submitted to OMB by the end of February. In fact, it was submitted on May 21, 1986. We received a copy of the NIOSH submission to OMB on May 27, 1986 and confirmed that the protocol submitted was essentially the same as the February, 1986 draft.

Drs. MacMahon and Zierler had previously provided us with a critique of the February, 1986 protocol. Although there are changes in the current submission, the overall considerations remain the same. Their scientific concerns are in the following areas:

(1) Inadequate provisions for evaluation of recall bias.

(2) Retention of substantial components of the questionnaire which are useless to the objectives of the study as stated, are an imposition on the study subjects' time, and constitute additions to the cost of data collection, processing and analysis.

(3) Retention of questions that are unnecessarily intrusive given the stated objectives of this study.

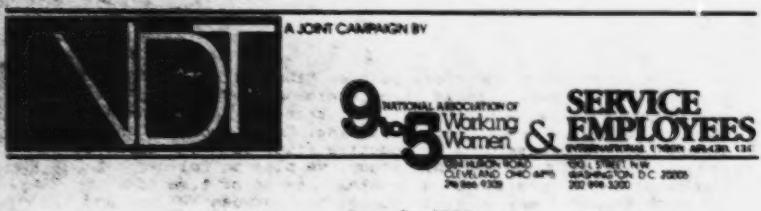
(4) Inadequate consideration of alternative study designs.

Considering Drs. MacMahon and Zierler's views, and NIOSH's unwillingness to incorporate recommended substantive changes in the protocol, BellSouth advised The Department of Health and Human Services (HHS) of our position on the study.

In our letter to HHS, we pointed out that it was not BellSouth's goal to prevent NIOSH from studying this subject or from relying, at least in part, on BellSouth employees for its study subjects. Rather, we emphasized our insistence that any study be capable of achieving the intended results of proving or disproving an association between VDT usage and adverse reproductive outcomes. We noted that further changes in the design of the study needed to be made. As an example, we suggested the use of a case control study based on a multi-industry review of medical records. Moreover, BellSouth committed to immediately join NIOSH in a review of the medical and insurance records of BellSouth employees to test the feasibility of this approach. NIOSH has rejected our above-outlined suggestions and offers.

We believe that the proposed protocol is lacking in two major considerations. As earlier stated, from a scientific viewpoint we conclude that the data generated will not be substantive enough to state if there is or is not an adverse relationship between VDT usage and pregnancy outcomes. From a perceptional viewpoint the study is too narrowly defined in that it only includes telecommunications workers. Therefore, other industries which are equally as VDT intensive, and the public at large, will not give significant credence to the findings, nor deem them applicable to their utilization of VDT's.

In conclusion, BellSouth considers it our obligation as an involved and affected corporate citizen to work to achieve a properly structured inquiry whose results will be reliable and meaningful. That is to say, the importance of the undertaking demands the best study vehicle or mechanism possible. However, in spite of our reservations, we will continue to support the concept of such a study. Thank you Mr. Chairman for affording BellSouth with the opportunity to state our position in this matter.



June 3, 1986

Joseph M. Gaydos, Chairman
Subcommittee on Occupational Safety and Health
Rayburn House Office Building, B348A
Washington, DC 20515

Dear Chairman Gaydos:

I am writing on behalf of the Service Employees International Union and 9 to 5, the National Association of Working Women to voice our support of the NIOSH "Reproductive Study of Women Who Work With Video Display Terminals". This study addresses an issue of major importance to our organizations. SEIU, along with our sister organization, 9 to 5, the National Association of Working Women, has actively advocated for research into the potential reproductive hazards associated with VDT use. SEIU and 9 to 5 have joined together in the "Campaign for VDT Safety" to work for guidelines over VDT use and on behalf of adequate funding for research aimed at identifying the health hazards associated with VDT use. This NIOSH study, using the Communication Workers of America's members at Bell South, will help to fill a void in scientific knowledge.

Since the initial identification of "problem pregnancy" clusters among VDT users, additional studies have substantiated initial concern over VDT use during pregnancy. Preliminary findings of a laboratory study reported at last month's International Scientific Conference on Work with Video Display Terminals in Stockholm led researcher Dr. Lars-Erik Paulsson to recommend shielding of VDTs because "at this point we don't know whether VDT work is completely safe or not."

With an estimated 15 to 19 million VDT users in the U.S. alone, it is imperative that we undertake the research necessary to begin to answer the questions raised with regards to the safety of VDTs. The NIOSH study is significant in several respects: the results of this study will help confirm the findings of studies in progress as well as document the experience of a group of women with intensive exposure to VDTs.

It is important that agencies, such as NIOSH with the credibility and expertise in large scale studies address this very important issue. The paucity of research in this area led SEIU, 9 to 5, and researchers at the Mt. Sinai Medical Center in New York to embark on a prospective study of the hazards to pregnancy of VDT use. In this study, we plan to follow thousands of VDT users over a lengthly period of time to thoroughly assess any possible connection between VDT use and reproductive problems. Hopefully, when these studies are complete, we will have answered some of the fundamental questions with regards to the level of risk and potential effects associated with VDT use.

In closing, we deplore the attempt of OMB to interject political interests in an area of scientific concern. The NIOSH study, as proposed, has gained the support of the overwhelming majority of scientific researchers in the field, management organizations, as well as organized labor. In the interest of furthering the pursuit of scientific inquiry and answering the concerns of millions of VDT users, I hope that this study will be allowed to go forward immediately.

Sincerely,

John J. Sweeney
International President
Service Employees International
Union, AFL-CIO, CLC

Karen Nussbaum
Executive Director, 9 to 5
National Association of
Working Women
President, District 925
Service Employees International
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STATEMENT by CHARLES A. PERLIK, Jr.

PRESIDENT, THE NEWSPAPER GUILD (AFL-CIO, CLC)

to the

HOUSE SUBCOMMITTEE ON HEALTH AND SAFETY

June 4, 1986

I would like to take the occasion of this hearing to express The Newspaper Guild's deep concern over the interminable delay that has dogged the National Institute for Occupational Safety and Health's proposed epidemiological study of birth abnormalities among VDT operators.

Plans for this study were initiated almost four years ago in response to a Newspaper Guild request following the discovery of clusters of birth abnormalities among Guild VDT operators at the Toronto Star and other operator groups. These plans have dragged through one delay after another since then, culminating in the Office of Management and Budget's outrageous rejection of the study protocol last December.

This study is of major importance in determining whether the clusters we have experienced are statistical aberrations, as some investigators have claimed, or are indeed the result of VDT work. The need for a resolution of this question has reached critical proportions as a result of the recent laboratory study at Sweden's Karolinska Institute, in which mice subjected to magnetic-field radiation duplicating VDT emissions suffered a significantly greater number of birth abnormalities than those not exposed.

This study was reported at the recent International Scientific Conference on Work with Display Units in Stockholm, along with other studies showing some evidence of adverse reproductive effects among laboratory animals similarly exposed to low-frequency radiation. These studies are far from conclusive, but they underscore the urgency of resolving the question of birth effects on VDT operators without further delay.

In this light, OMB's intervention in an area totally outside its field of competence is a scandal. In rejecting the NIOSH protocol, it chose to accept the opinion of consultants retained by BellSouth despite the protocol's approval by a panel of peer reviewers. The characterization of this action by Dr. Philip Landrigan, former director of NIOSH's Division of Surveillance, Hazard Evaluations and Field Studies, as "scientific meddling" and "an unwarranted intrusion into the scientific authority of the agency" is eminently accurate.

NIOSH has nevertheless resubmitted its study protocol, taking account of OMB's objections. Further delay is unthinkable, and we urge the Subcommittee to exert all the influence at its command to assure speedy approval of the revised protocol. With close to 10 million VDTs now in U.S. offices and the prospect of many millions more soon to come, their hazard potential cannot continue to go unresolved.

U. S. HOUSE OF REPRESENTATIVES

EDUCATION AND LABOR

SUBCOMMITTEE ON HEALTH AND SAFETY,
REPRESENTATIVE JOSEPH M. GAYDOS
(D-PA.), CHAIRMAN

STATEMENT OF

JAMES P. DUNN

On Behalf of

AT&T

June 4, 1986

Mr. Chairman and members of the subcommittee, my name is James P. Dunn, and I am the Associate Medical Director for AT&T. AT&T is a corporation primarily engaged in the business of telecommunications equipment and services. My specialty as a physician is in occupational medicine and in epidemiology.

AT&T has a continuing commitment to the safety and health of its employees and is, more specifically, concerned about the issue at hand, the safety and health of its employees and of all employees who are anywhere using video display terminals in the workplace. That is why I am pleased to submit this testimony to you on behalf of AT&T.

AT&T supports the objective of the study proposed by NIOSH to measure the adverse pregnancy outcomes among employees who work with VDTs with comparable employees who do not. When NIOSH originally approached AT&T, AT&T agreed to discuss a possible research effort on this subject. Discussions were held in late 1983 and early 1984, and emphasis was placed on the need for multi-company and multi-job representation so that the study would reflect as well as possible the broad range of VDT use in business operations. AT&T continues to support such an approach.

In the early stages of our discussions with NIOSH, we understood NIOSH was contacting many employers and labor groups in several industries--communications, insurance, computer manufacturing, airlines, newspapers, and government services. We

understood the intent of the study to identify a broad cohort across multiple industries, and we accepted this as an appropriate methodology. The proposed study was then described as follows:

A cohort of married, female, non-management workers in the reproductive ages, within a limited geographic area, would be identified and defined as to use or non-use of VDTs. They would be observed over time to ascertain outcomes of pregnancies occurring to them. A sufficient number of women would be recruited so that at least 1,500 would remain at the end of the study in each group. A questionnaire would be self-administered at three intervals, 9 months apart, to gather information on their general and reproductive health, occupational history, personal habits (such as the use of alcohol, caffeine, and tobacco), and characteristics of their duties and workstations. The time required to complete the questionnaire would be 20 to 40 minutes the first time; 10 to 20 minutes the two succeeding times. Complete, chronologic employment histories would be ascertained from personnel records. Data would be analyzed after the completion of the first questionnaire, and again after the second and third contacts, to examine the historical experience of the subjects regarding VDT use, and their pregnancy outcomes. The length of the study would be about 3 years.

AT&T agreed to cooperate with NIOSH in making available work force information for planning purposes. AT&T, however, told NIOSH that this degree of cooperation did not commit it to participation. Such a commitment could only be made after a protocol concerning the

study had been submitted and the company had had an opportunity to review it. In the course of 1984, AT&T provided to NIOSH information on employee work force and arranged for NIOSH investigators to visit work sites.

The protocol was received on the 20th of November 1984. When we received the protocol, we discovered that the proposed study had been narrowed to one industry only--telecommunications; that it was further narrowed to one occupation--telephone operators; and that it was even further limited to two employers--BellSouth and AT&T.

The protocol presented a combination of a retrospective study and a prospective study. Emphasis was placed on the superior value of a prospective study, in which the two groups could be monitored through a number of years to determine comparative pregnancy outcomes. It was recognized that a retrospective study had a serious weakness in terms of biased recall.

We responded at that time that we remained receptive to cooperation in a multi-industry study focused on VDT use and pregnancy outcome but that the single-industry, single-occupation study was not appropriate.

In the process of questioning the merits of a single-industry study, we also pointed out, along with BellSouth, that NIOSH had developed this single-industry proposal without being aware of the changes that were happening in both BellSouth and AT&T. In

particular, the control population of long-distance operators was scheduled to undergo two major changes that would no longer keep it as a non-VDT user population. First, a substantial number of them--about 40%--were being transferred from AT&T to BellSouth as part of the follow-up agreements to the divestiture of the Bell System. BellSouth was placing these operators in stations that included video display terminals. Second, AT&T was also converting the stations of the operators who were remaining with AT&T by adding video display terminals for more efficiency in the handling of customer service. This conversion is underway and will be completed by the end of this year. The significance of these changes is that a prospective study is no longer possible because there is no longer an identifiable control group of non-VDT users.

NIOSH has continued to hope that a prospective study can be developed with these two groups of telephone operators but has recognized the likelihood of having to limit the project to a retrospective study only.

Nevertheless, the sample frame remains restricted to telephone operators. We continue to doubt the value of such a narrow scope because of the questionable generalizability of the results especially where the study is limited by necessity to a retrospective survey only.

A second set of concerns which we have expressed relate to the inclusion of testing for stress and ergonomics in the protocol. The effects of stress and ergonomics on adverse pregnancy outcomes are not at all well substantiated or measurable. These variables have not been established as confounders to the degree that smoking, alcohol and medications have. In particular, the measurement of stress as proposed in the protocol is limited since it would be based on recall and does not differentiate stress resulting from non-job related situations. The measurement of stress involves almost total subjective evaluation. The questionnaires proposed to measure stress have not been validated in telephone interviews. Indeed, peer reviewers on this issue favored a limited assessment of this factor.

The inclusion of ergonomics offers little or no application to other companies' work situations. No hard measurement of ergonomics is proposed by the protocol, just descriptive terminology from superficial telephone surveys. This may be interesting but has limited validity, use, applicability, and generalizability.

The original intent and design of the study was geared to determine adverse pregnancy outcomes from VDT exposure. Yet, the protocol would examine stress and ergonomics. If NIOSH wishes to study these factors, a different research design is needed.

The Peer Review Panel used by NIOSH has expressed reservations about the design of a retrospective study, the outcome measures, the need for additional control groups, and the measures of stress and ergonomics.

AT&T is committed to assuring the continued health and safety of its employees. We would support a study on adverse pregnancy outcomes which is valid, reliable and has generalizable conclusions. The original basis underlying the study which enlisted our support has been substantially altered: The scope of the study has been expanded beyond the effect of VDTs on pregnancy outcomes and the base of the study group has been narrowed from a multi-employer, wide spectrum user-body to a single-employer, single-job target. We believe this affects the application of any results of the study and hampers its utilization by employers and employees nationwide.

We urge that reconsideration be given to the proposal by NIOSH in light of comments from the panel and ourselves.

On behalf of AT&T, thank you, Mr. Chairman and members of the subcommittee, for the opportunity to present our views on this important issue.